EXHIBIT 34

IN RE: OPIOID LITIGATION
Civil Action No. 17-md-2804 PHARM
In the Circuit Court of Cobb County, Georgia

General Expert Report of Carmen A. Catizone, MS, RPh, DPh

Contents

Executive Summary

This report provides the opinions I intend to offer at trial, and the reasons and bases for those opinions regarding: (1) the standard of care and the usual and customary practices of pharmacies with respect to dispensing of opioids; and (2) the pharmacy practices of Kroger and Publix as determined by my review of documents provided to and requested by me. This report refers to Kroger and Publix collectively as "Defendants" or the "Chain Pharmacies." My general opinions would also apply to all other Chain Pharmacies.

The issues examined specifically concern Defendants' actions with respect to maintaining effective policies and practices to guard against the diversion of prescription opioids, their failure to maintain and adhere to well-established pharmacy standards of care, and their dispensing of opioids despite obvious and significant red flags.

A summary of my opinions is below:

- The practice of pharmacy is governed by well-defined laws and regulations, both at the national and state-wide levels.
- The practice of pharmacy is subject to established and well-known standards of care, including requirements for the careful evaluation of prescriptions and efforts to guard against the diversion of medications into non-medical or illegitimate use.
- Dispensing drugs for non-medical purposes or under circumstances which a pharmacist otherwise knows or should know present a significant risk for diversion falls outside the defined practice of pharmacy and standards of care.
- By law, a pharmacist may only dispense controlled substances pursuant to a prescription that is valid and that has been issued by a licensed practitioner for a legitimate medical purpose in the usual course of his or her professional practice.
- Federal and state controlled substances laws and regulations require Defendants to maintain effective controls for a closed system of distribution and dispensing of opioids that guards against diversion.
- Corporate oversight includes established practices of pharmacies that should incorporate top-down compliance programs using data readily available to the corporation to guard against diversion. Oversight also should support, and not impede, pharmacists in complying with laws and regulations related to the dispensing of controlled substances.
- Corporate oversight should set patient care and integrity expectations and provide tools for pharmacists to exercise practices to adhere to appropriate laws, regulations, and pharmacy standards of care in dispensing controlled substances.
- Chain pharmacies exert a great deal of control over, and oversight of, their pharmacies and pharmacy employees which directly impacts the dispensing of controlled substances.
- Chain Pharmacies, through the control they exert over their agent pharmacies, pharmacists, and pharmacy employees, are responsible for ensuring all dispensing of controlled substances is carried out in accordance with applicable laws, regulations and standards of care.

- Defendants failed to timely implement and apply necessary controlled substance diversion policies across their pharmacy stores.
- Once controlled substances diversion policies were developed, Defendants failed to effectively monitor, audit and enforce the policies across their pharmacy stores.
- Defendants implemented employment evaluation policies and performance metrics that impeded their pharmacists' efforts to comply with laws and regulations and meet standards of care.
- Defendants failed to adequately staff their pharmacies to meet the requirements of the Controlled Substances Act (CSA) and state law.
- Red flags are not a novel or unknown concept to pharmacists, pharmacies, or Defendants. Red flags are common-sense warning signs that have long been an important component of controlled substance pharmacy best practices.
- Red flags of diversion are known or should be known to pharmacists in the usual and customary practice of pharmacy.
- "Red flags" commonly recognized in pharmacy practice with respect to prescription opioids include:
  - Patients traveling long distances to their pharmacy or prescriber;
  - Patients obtaining multiple opioid prescriptions from different prescribers;
  - Patients traveling to multiple pharmacies to fill opioid prescriptions;
  - Prescriptions for an opioid and benzodiazepine, with or without an additional muscle-relaxer, which, when combined, intensifies the risk of overdose and death;
  - Prescription(s) for an excessive quantity of an opioid, or multiple opioids, on the same day or within an overlapping period of time;
  - "Pattern" prescribing, such as when prescriptions are presented by multiple patients for the same medications, same strengths, approximately same quantities, and directions for use;
  - Early refills, that is, when an opioid prescription is presented for refill more than five days before the patient's previous prescription should have run out;
  - Patients prescribed opioids for more than six months;
  - Patients who seek to fill two short acting opioid drugs on the same day;
  - Patients who pay cash for opioid prescriptions; and
  - Patients who behave suspiciously.

  These red flags have all been identified in various DEA enforcement actions and in guidance from industry trade groups. Defendants themselves identified similar or other "red flags" as indicative of possible diversion.
- As each red flag is a potential indication of diversion, when a prescription is presented with multiple red flags the likelihood of diversion increases greatly.
- Many of the red flags identified above are easier to identify through data collected and maintained at the corporate level.
- Opioids are extremely addictive and highly subject to abuse. As a result, all red flags are concerning.
- Every red flag must be resolved before each prescription for a controlled substance is dispensed. The pharmacist must also document how that red flag was resolved. The

performance of the red flag analysis required by the pharmacy's corresponding responsibility was especially critical when those in the practice of pharmacy became aware that opioid diversion and misuse reached epidemic proportions.

- The guiding elements establishing adequate due diligence are known to Defendants and should be included in their policies and CSA recordkeeping requirements. These common elements for adequate due diligence include:

  (a) the pharmacy must accurately identify and document all red flags raised by the prescription, patient, and prescriber;

  (b) the pharmacy must reasonably collect complete, relevant, and accurate information concerning each red flag;

  (c) the pharmacy must independently evaluate the collected information to determine whether the evidence is reliable and whether, as a whole, the evidence adequately resolves each red flag; and

  (d) lastly, the pharmacy must clearly and explicitly document their evaluation of the evidence and their reasoning supporting their judgment to dispense the prescription.
- Defendants possess dispensing data and other information collected from their individual pharmacies which could have been used to prevent diversion. Dispensing data should have been reviewed by each Defendant to identify patterns of diversion and to create and assess policies and procedures and training materials which proactively identified patterns of diversion. Defendants should have used the information gleaned from that proactive analysis to inform their pharmacy staff of these patterns and to develop policies, procedures, and training materials for its pharmacies. Each Defendant should have also developed tools and programs to alert its pharmacists of these red flags at the time each prescription was presented.
- Corporate performance metrics focused on increasing dispensing of prescriptions, increasing sales, and lowering customer wait times can place pharmacists in conflict with legal requirements, including performing the pharmacy's corresponding responsibility. A pharmacist pressured to work too quickly could miss dangerous drug interactions and may not have sufficient time to perform safety reviews and is then at risk of missing red flags of diversion. The high stress and chaotic environment is exacerbated by staffing challenges at the Chain Pharmacies. Likewise, a focus on high volume and minimizing customer wait times place demands on pharmacists impacting the proper review of prescriptions to ensure their appropriateness and validity and to resolve any red flags.
- Documentation and record-keeping are important tools in preventing diversion of controlled substances.
- Defendants failed to provide their pharmacists with data, information, and the tools necessary to assist their pharmacists in fulfilling their corresponding responsibility duties, including but not limited to, utilizing dispensing data to identify patterns, trends, and practitioners possibly involved in diversion as well to recognize and resolve red flags. The failure to provide such data, information, and tools likely caused diversion of significant quantities of controlled substances, particularly opioids, outside of the closed distribution and dispensing system for controlled substances.
- Defendants failed to maintain effective controls to guard against diversion.

A detailed discussion of the reasons and bases for each of these opinions is set forth below. The opinions expressed are based on my experience and expertise in the practice and regulation of pharmacy, as well as on the review of numerous documents. A complete list of the materials I reviewed is attached hereto as Exhibit B.

I offer my opinions herein to a reasonable degree of professional certainty. I reserve the right to supplement this report if a production is made of additional notes and due diligence materials and if any other new information becomes available.

Introduction

The opinions presented are based on my experience and expertise in the practice and regulation of pharmacy. From 1988 to 2020, I served as the Executive Director and the CEO of the National Association of Boards of Pharmacy ("NABP"). NABP was established as an impartial organization in 1904. The members of NABP are the state agencies that regulate the practice of pharmacy. NABP supports the state boards of pharmacy by developing, implementing, and enforcing uniform standards for the purpose of protecting the public health. NABP also helps state boards of pharmacy protect public health and safety through its pharmacist license transfer, pharmacist competence assessment, and accreditation programs. As Executive Director I oversaw the day-to-day operations of the NABP. A significant focus of my work was in the area of pharmacy regulations through state boards of pharmacy and other governmental and private entities responsible for regulating pharmacists, technicians, pharmacies, wholesale distributors, and other entities in the pharmaceutical supply chain.

I previously served as liaison to the Food and Drug Administration ("FDA") and the Drug Enforcement Agency ("DEA"). I served as a Governor of the Pharmacy Technician Certification Board ("PTCB") and Chair of the PTCB Certification Council. I am also a past President of the National Pharmacy Manpower Project and the National Conference of Pharmaceutical Organizations ("NCPO") as well as a past member of the United States Pharmacopeia ("USP") Board of Trustees.

I have been the recipient of many honors and awards including an Honorary Doctor of Pharmacy from the State of Oklahoma, the Certificate of Appreciation from the District of Columbia, two FDA Commissioner Special Citations, the University of Illinois Alumnus of the Year, American Druggist Magazine Pharmacist of the Year, and the University of Illinois, College of Pharmacy, Alumni Association's Sister Margaret Wright Graduate Award.

I received a Bachelor of Science degree in pharmacy and a Master of Science degree in pharmacy administration from the University of Illinois at Chicago.

I have been recognized as an expert witness in state and federal district court cases numerous times. In the past fifteen years I have testified as an expert witness in the following litigations:

Trial: Expert Witness, United States District Court, Northern District of Ohio, In re Nat'l Prescription Opiate Litig, Case No 17-md-2804. Subject Standard of Pharmacy Practice.

Trial: Expert Witness, United States District Court Northern District of California, The City and County of San Francisco v. Purdue Pharma, Case No C18-07591 CRB. Subject: Standard of Pharmacy Practice.

Trial: Expert Witness USA Office-Eastern District of Michigan, US v. Abiodun Fabode, October 30, 2019. Subject: Distribution of controlled substances.

Trial: Expert Witness USA Office-Southern District of New York, US v Lena Lasher, May 8, 2015. Subject: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Southern District of New York, US v Lee, et al, September 10, 2014. Subject: Distribution of controlled substances.

Trial: Expert Witness USA Office-Northern District of Ohio, US v Rovedo, et al, October 10, 2012. Subject: Distribution of controlled substances.

Trial: Expert Witness USA Office-Northern District of California, San Francisco Division, US v Napoli, et al, October 4, 2012. Subject: Distribution of controlled substances.

Trial: Expert Witness USA Office-Northern District of California, San Francisco Division, US v Michael Arnold & Jeffrey Herholz, February 16, 2012.

Trial: Expert Witness USA Office-District of Massachusetts, Boston Division, US v Baldwin Ihenacho, January 18, 2012. Subject: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Eastern District of Texas, Beaumont Division, US v David Vogel, et al, June 30, 2010. Subject: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Western District of Missouri, Western Division, US v Rostie, et al, June 28, 2010. Subject: Distribution of controlled substances.

Trial: Expert Witness USA Office-Western District of North Carolina, Charlotte Division, US v Woody, et al, August 17, 2009. Subject: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Middle District of Florida, Orlando Division US v Jude LaCour, et al, April 14, 2009. Subject: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Twentieth Judicial District of Kansas, Rice County: US v Hogan's Pharmacy, March 12, 2009. Subject: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-Eastern District of New York: US v Wahidullah Hossaini, November 12, 2008. Subject: Distribution and possession of oxycodone and hydrocodone.

Trial: Expert Witness USA Office-Eastern District of New York: US v Quinones, et al, October 27, 2008. Subject: Distribution of prescription drugs over the internet.

Trial: Expert Witness USA Office-District of Maryland: US v Steven A Sodipo, et al, July 7-8, 2008. Subject: Distribution of prescription drugs over the internet.

Trial: USA Office-Northern District of California: In the Matter of the Accusation Against: US v International Pharmaceutical Services Afshin Adibi, Respondent, November 28, 2007.

Trial: Expert Witness USA Office-District of Minnesota: US v Christopher Wm. Smith, November 15, 2006.Subject: Illegal distribution of prescription drugs.

Hearing: DEA In The Matter of: United Prescription Services, Inc, April 10, 2007. Subject: Illegal distribution of controlled substances.

Hearing: DEA In The Matter of: Trinity Healthcare Corporation, d/b/a Oviedo Discount Pharmacy (No. 06-4), June 1, 2006. Subject: Illegal distribution of controlled substances.

A copy of my curriculum vitae is attached as Exhibit A.

I am being compensated for my time at an hourly rate of $300.00. My compensation is not dependent on the outcome of this proceeding.

The Practice of Pharmacy – Standard of Care

The mission of pharmacy practice is "to serve society as the profession responsible for the appropriate use of medications, devices, and services to achieve optimal therapeutic outcomes."[1] The path to becoming a pharmacist involves years of specialized training, education, and licensure and ongoing continuing education to remain current with new drugs, devices, therapies, and standards.

[1] Vision and Mission for the Pharmacy Profession, American Pharmacists Association, adopted by the APhA House of Delegates (March 1991).

Standards of care define a competent level of care expected of a pharmacist dispensing medications and providing direct patient care. Standards of care direct and seek to maintain safe and clinically competent practitioners. Pharmacists are not mere sellers of medications prescribed by doctors. They are licensed professionals with independent duties and obligations which have evolved over the past century. Those practices and their standard of care are reflected in national and state laws and regulations as well as pharmacy practice organizations and industry guidance. Moreover, pharmacists and pharmacies are entrusted with a key role in helping ensure that people achieve the best results from their medications.

The practice of pharmacy has developed into a fairly uniform standard of practice across the U.S. State and federal regulations setting forth state and national requirements across the states identify the responsibilities of the pharmacy and its agents (pharmacists and technicians) and desired patient outcomes uniformly, with only limited variances in patient care and regulatory areas. In the usual and customary practice of pharmacy, a pharmacist must carefully evaluate every prescription presented for dispensing. The evaluation is a multi-component process that examines whether the prescription is appropriate and safe for the patient and, if issued for a controlled substance, there is an additional responsibility for a heightened evaluation to determine that the prescription is valid and issued for a legitimate medical purpose.

As discussed further below, the evaluation process begins with an assessment of the prescription to determine if it is appropriate and safe for the patient. The pharmacist is required to review the prescription in the context of patient factors (allergies, weight, etc.), reason for the issuance of the prescription (condition, diagnosis, and/or symptoms), medications the patient is currently using (to identify any potential adverse effects and adverse drug reactions or interactions, including ineffective drug therapy, significant side effects, significant drug interactions, over-utilization of a drug, duplicate drug therapy, and abuse, misuse or noncompliance with drug therapy), and applicable lifestyle factors (smoking, alcohol or drug use, etc.). This process is commonly referred to as Drug Utilization Review ("DUR"). It is also referred to as Drug Utilization Evaluation ("DUE") or Medication Utilization Evaluation ("MUE").

It has long been understood that dispensing drugs for non-medical purposes or which a pharmacist otherwise knows or should know present a significant risk for diversion falls outside the defined practice of pharmacy and standards of care. As part of their assessment, pharmacists must consider whether what is presented to them as a "prescription" is in fact valid and issued by a licensed professional in the usual course of professional practice. This common-sense requirement is codified into laws and regulations including, at the federal level, the Comprehensive Drug Abuse Prevention and Control Act of 1970 ("Controlled Substances Act" or "CSA"), 21 U.S.C. §§ 801 *et. seq.*.) as well as pertinent state laws. Among other requirements, a pharmacy registrant must provide effective controls and procedures to guard against theft and diversion of controlled substances. 21 C.F.R. 1301.71. For a controlled substance prescription to be valid, a pharmacist is obligated to determine whether the prescription was issued for a legitimate medical purpose. 21 C.F.R. 1306.04(a). A prescription for a controlled substance may only be filled by a pharmacist, *acting in the usual course of his professional practice* and either registered individually or

employed in a registered pharmacy, a registered central fill pharmacy, or registered institutional practitioner (emphasis added). 21 C.F.R. 1306.06.

Corporate Oversight

Pharmacies are permitted or licensed to operate with important responsibilities and duties in the practice of pharmacy. In exchange for the privilege of holding a license to distribute and dispense controlled substances, Pharmacies have the responsibility of ensuring that their controlled substances are not diverted and/or subject to abuse and misuse. Pharmacies have operating systems and methods to dispense, store, and retain prescriptions and prescription dispensing data and records. The information must be readily retrievable when requested by state authorities and utilized to identify patterns of diversion, audit the dispensing of their pharmacists, develop training programs and information for their pharmacy and management personnel, investigate suspicious prescribers, patients, and pharmacists, and prevent diversion of controlled substances. These responsibilities are reflected in the Controlled Substances Act and relevant state law. Those responsible include the pharmacist, technician, and the pharmacy. State regulations and the NABP Model Act define responsible entities as individuals, partnerships, corporations, associations, trusts, or other entities without qualification. Responsibilities extend to the hiring, training, and managing of pharmacy personnel as well as the supporting policies, procedures, and systems that promote public health and safety and assist in the identification and prevention of the diversion of controlled substances. The large Chain Pharmacies operate pharmacies in multiple states and employ thousands of pharmacists and pharmacy technicians who support pharmacists, in various roles.

Although Chain Pharmacies market their specific images and offer varying services, the infrastructure is quite similar. A chain pharmacy company is defined as one which operates four or more pharmacies which include traditional drug store formats as well as pharmacies located in supermarkets, mass merchant, and discount stores. Pharmacy chains tend to be much larger than independent drug stores and to have centralized operational processes – prescription processing, reimbursement submissions, product ordering and distribution, and policies and procedures.[2]

Individual pharmacies are managed by a store manager. The store manager is a salaried position with incentives based upon performance metrics established by the chain — typically, store performance, inventory, and customer satisfaction. Store managers have operational control of the store and all of its departments. The store manager is responsible to a supervisor (sometimes referred to as district or regional pharmacy manager or leader) who oversees a number of stores within a shared geographic area or common division. The regional or district pharmacy managers typically report directly to corporate liaisons.

[2] NACDS Chain Member Fact Book, 2019-2020.

Pharmacy chains exert a great deal of control over, and oversight of, their pharmacies and pharmacist employees, which directly impacts the dispensing of controlled substances. Chain pharmacy technicians, whose role has evolved over time, assist pharmacists through the completion of tasks, including but not limited to, accepting the prescription(s) from patients, entering the prescription information into the dispensing system, and assisting in the assessment of the validity of prescriptions. As a result, Chain Pharmacies and their agents are responsible "Persons" under the CSA. The chain pharmacy corporation is ultimately responsible for ensuring all dispensing of controlled substances is carried out in accordance with applicable laws, regulations, and standards of care.

State laws require that every pharmacy be overseen by a pharmacist-in-charge or responsible pharmacist. The pharmacist-in-charge is accountable for the operation and management of the pharmacy within the required legal context of state and federal laws and regulations and corporate management and control. The pharmacist-in-charge is responsible to the store manager and a regional or district pharmacy manager. The regional or district pharmacy manager is responsible to a corporate liaison.

Chain Pharmacies have important responsibilities and duties in the practice of pharmacy. Chain Pharmacies are subject to a number of legal obligations, including those discussed in this report. A top-down compliance program which includes audits to determine whether written policies and procedures are being observed is important to ensuring that the pharmacy and its pharmacists are satisfying their obligations and meeting the applicable standard of care. Chain Pharmacies must maintain systems and methods to store and retain prescription dispensing data and records. Documentation related to the dispensing of controlled substances is a critical component of any system or program. Documentation identifies critical factors, such as red flags, whether the pharmacist resolved the red flag(s), and information alerting to the occurrence or possibility of diversion. It also provides proactive direction to other pharmacists in the future. Chain Pharmacies must utilize their information to identify patterns of diversion; audit the work of their pharmacists; train their pharmacy personnel; investigate suspicious prescribers, patients, and pharmacists; and prevent diversion of controlled substances.

A pharmacy cannot absolve itself of its responsibilities under the CSA, particularly the "corresponding responsibility" discussed below, by placing unilateral responsibility on the individual pharmacist dispensing the prescription(s). A corporate Chain Pharmacy is also responsible for its operations including individual pharmacy stores and employees. Policies and procedures must be in place for all areas of operation related to controlled substances and the conduct of its pharmacy staff. The corporate entity is responsible for collecting and monitoring data related to the individual pharmacies and pharmacists and dispensing of controlled substances in order to comply with the CSA requirements outlined above and within state laws and regulations. The corporate Chain Pharmacy is also responsible for providing its pharmacy stores and employees access to databases, information, training, and tools (utilizing whatever infrastructure necessary, such as intranet and internet systems) to assist in determining the validity of a prescription, such as whether a prescriber is appropriately licensed and other due diligence related to the filling and validity of a controlled substance prescription.

Pharmacies must also ensure adequate staffing. This includes ensuring the presence of a licensed pharmacist at all times the pharmacy is operating, and appropriate staffing levels to safely and effectively evaluate and dispense medications and counsel patients. This standard of practice is also a regulatory requirement and encompasses additional requirements of the pharmacist-in-charge, including but not limited to, pharmacist coverage at all times the pharmacy is open and the ratio of pharmacists to pharmacy technicians.

Corporate pharmacy chains operate as diverse retail businesses. They place responsibilities on their management and requirements and expectations on their staff that are not inherently or intuitively part of the practice of pharmacy. These include various business goals such as the pace at which prescriptions are filled, including meeting promised wait-time goals and the volume of sales or provision of additional promotional services such as immunizations and vaccinations. Pharmacy chains also set more directly revenue-related goals. At times, these corporate goals obstruct the performance of pharmacists' professional obligations.[3] An example can be found in the inherent conflict between performance metrics that require pharmacists to fill certain volume of prescriptions or to limit customers' wait time and the pharmacist's ability to conduct appropriate due diligence on a prescription for controlled substances. In addition, basing pharmacists' incentive pay on customer satisfaction and the expected dissatisfaction that is likely to result from a pharmacist declining to fill a prescription due to deficiencies in the prescription or suspected diversion creates a conflict between the pharmacist's responsibility to ensure optimal patient outcomes and corporate business measures. There is also a duty to ensure compliance with the law through a corporate culture that directs and firmly supports pharmacists in exercising their professional judgment and discharging their legal responsibility to decline to fill and subsequently report prescriptions or other conduct that suggest diversion. Too often, pharmacists report being discouraged by management from raising concerns about prescribers or practices or declining prescriptions, or facing time and volume pressures or priorities that make compliance an impossible or devalued part of their job responsibilities.

Background Requirements

A. DUR Process and Prescription Drug Monitoring Programs

The pharmacist's historical role has been to serve as the medication therapy expert and assuring that the medication prescribed is appropriate for a particular condition or symptom. Ascertaining the appropriateness of a patient's medication therapy includes, for example, verifying that the dosage and duration of the treatment is correct for the condition and/or symptoms, does not conflict with the patient's allergies or individual characteristics such as metabolism rate, does not interact with other medications the patient is taking, and that the patient is not abusing or misusing the medication. These traditional roles and duties were codified for Medicaid beneficiaries with the

[3] Munger Mark A.; Gordon, Elliot; Hartman, John; Vincent, Kristen; Feehan, Michael, *Community pharmacists' occupational satisfaction and stress: a profession in jeopardy?*, J. Am. Pharm. Assoc., May-Jun 2013; 53(3):282-96. DOI:10.1331/JAPhA.2013.12158.

passage of the Omnibus Budget reconciliation Act of 1990 (OBRA '90) and extended further beyond Medicaid beneficiaries by state pharmacy boards.

OBRA '90 added to the federal statutory requirements governing participation in the federal-state partnership program officially designated Grants to States for Medical Assistance Programs, and known in everyday parlance as the Medicaid program. The federal statute laid out responsibilities for pharmacies to ensure that prescriptions were appropriate for, and understood by, Medicaid beneficiaries. OBRA '90 had several major components: 1) Prospective Drug Use Review, 2) Retrospective Drug Use Review, 3) Assessment of Drug Use Data, and 4) Educational Outreach Programs.[4]

Implementing regulations governing DUR came into effect on January 2, 1993, as an interim final rule. HHS's Health Care Financing Agency (HCFA), which oversees Medicaid, finalized the regulation on September 23, 1994. *See* 59 FR 48811-48825. The final rule requires "review of drug therapy before each prescription is filled or delivered to a recipient" for purposes of "detect[ing]" issues such as "therapeutic duplication, adverse drug-drug interaction," and "clinical abuse and/or misuse." The rule also mandates patient "[c]ounseling and maintenance of patient profiles by the pharmacist."

During the rulemaking process, "[o]ne commenter suggested that instructions for compliance with prospective DUR should go to the pharmacist and **not** the pharmacy." The government's response stated, "We believe that the instructions for compliance with prospective DUR should be directed to the pharmacies," noting that "[t]he owners or managers of pharmacies, as Medicaid providers, are responsible for furnishing their staff with information pertaining to DUR." *See*, p 48816, first column. States took action to require OBRA 90's mandates for the states to improve understanding of medications to all patients to assure uniformity of care and avoid establishing differing standards of care among patients.

A summary of the requirements is included in the Table below:[5]

[4] Vivian, J.C., & Fink III, Joseph, *OBRA '90 at Sweet Sixteen: A Retrospective Review,* U.S. Pharmacist, March 20, 2008.
[5] *Id.*

Table 1

OBRA '90 Pharmacy Provisions

The primary focus of pharmacy activities required under OBRA '90 include:

Prospective Drug Utilization Review

Is the prescription necessary and appropriate? Factors to consider:

- Over/under utilization
- Therapeutic duplications
- Drug-disease interactions
- Drug-drug interactions
- Incorrect dosage or duration of treatment
- Drug-allergy interactions
- Clinical abuse and/or misuse

Patient Counseling Standards

An offer to have a pharmacist counsel the patient must be made. Items to address:

- Name of drug (brand name, generic, or other descriptive information)
- Intended use and expected action
- Route, dosage form, dosage, and administration schedule
- Common side effects that may be encountered, including their avoidance and the action required if they occur
- Techniques for self-monitoring of drug therapy
- Proper storage
- Potential drug-drug or drug-food interactions or other therapeutic contraindications
- Prescription refill information
- Action to be taken in the event of a missed dose

Maintaining Patient Records

Keep accurate and up-to-date patient profiles. Information to include:

- Patient's full name
- Address and telephone number
- Date of birth or age
- Gender
- Drug profile
- Pharmacist comments
- Chronic conditions, allergies, and drug reactions

The DUR process is a foundational component of the practice of pharmacy and defined further by state practice acts and rules. It is also a key tenet of the standards of care for the practice of pharmacy.

The DUR process is especially important for the assessment of the appropriateness of prescribed controlled substances, such as opioids, which have a high propensity for abuse and addiction. Such an assessment should examine over-utilization, inappropriate duration of treatment, drug interactions, and therapeutic duplication in order to provide appropriate care while also identifying abuse and misuse of these dangerous drugs. Communities where opioids were readily available

and prescribed liberally were the first areas to experience markedly increased prescription opioid abuse.

Realizing that these general DUR provisions were not effectively preventing the escalation of opioid over-use and abuse, states revised and expanded practice acts and rules and increased their support for, and reliance on, Prescription Drug Monitoring Program (PDMPs).

A PDMP is an interactive database that facilitates the sharing of health information related to controlled substance prescriptions. PDMPs provide clinicians and pharmacists with information on a patient's controlled-substance prescription history and can be a useful tool when considering treatment options and screening patients who may at risk for abuse or diversion. Chain Pharmacies, along with independents, are the primary sources of the data contained within a PDMP and they play a critical role in ensuring that complete and comprehensive data is provided so as to contribute to the usefulness of the database.

The CDC recognizes that:

> PDMPs improve patient safety by allowing clinicians to:
>
> - Identify patients who are obtaining opioids from multiple providers.
> - Calculate the total amount of opioids prescribed per day (in MME/day).
> - Identify patients who are being prescribed other substances that may increase risk of opioids—such as benzodiazepines.[6]

Information in PDMPs is potentially life-saving and allows pharmacists to identify patients who may be misusing prescription opioids or at risk for overdose. [7]

The first PDMP program was enacted by New York State in 1918 to monitor prescriptions for cocaine, codeine, heroin, morphine, and opium. Pharmacists were required to report copies of prescriptions to the New York State Health Department within 24 hours. California initiated its prescription monitoring program in 1939. The enactment began the "paper era" of PDMPs. In 1989, Oklahoma required that prescription monitoring data be communicated electronically. State PDMPs continued to grow through the 1990s and early 2000s, with 70% of program establishments occurring in the first 15 years of the 21st century.[8]

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[6] https://www.cdc.gov/drugoverdose/pdf/pdmp_factsheet-a.pdf

[7] CDC, Prescription Drug Monitoring Programs (PDMPs): What Healthcare Providers Need to Know, https://www.cdc.gov/drugoverdose/pdmp/providers.html.

[8] Prescription Drug Monitoring Program Training and Technical Assistance Center, *History of prescription drug monitoring programs,* Brandeis University (Mar. 2018), pdmpassist.org/pdf/PDMP_admin/TAG_History_PDMPs_final_20180314.pdf (accessed 1/12/2024).

The DUR process and state PDMPs are key instruments for pharmacies to identify and prevent diversion. Each of the Defendants recognized the important role PDMPs play in identifying and analyzing potential signs of diversion.

As rates of PDMP participation increase, incidents of doctor shopping and prescribing of certain controlled substances decline. The data suggest that PDMP utilization helps to promote medically warranted prescribing and dispensing, and assists in detecting possible controlled substance misuse and diversion.[9]

B. Controlled Substances

Controlled substances are drugs which pose a significant risk to the public. Given the dangerous nature of these drugs, pharmacy practice dictates that several controls be put in place to secure these drugs and to ensure that they are dispensed only to patients holding a valid prescription, issued by a DEA licensed prescriber, and issued for a legitimate medical purpose by a practitioner acting within the usual course of the practitioner's professional practice. Providing prescription drugs for non-medical purposes or which present significant risk for diversion is not considered part of the practice of pharmacy.

1. The CSA

In addition to the above requirements and standards of care, the regulation of the practice of pharmacy includes specific provisions for the manufacture, importation, possession, use, and distribution of controlled substances. Controlled substances require more stringent requirements and regulations than those for non-controlled substances because of the potential for abuse, harm, and diversion. The CSA was signed into law on October 27, 1970, effective May 1, 1971, to address the need for these more stringent considerations and to regulate all participants in the controlled substances' supply chain. The CSA contains three titles: Title I that addresses rehabilitation programs for individuals who abuse controlled substances; Title II that defines and outlines the processes for the registration and distribution of controlled substances; and Title III that concerns the importation and exportation of controlled substances. All state Pharmacy Practice Acts and Regulations incorporate the CSA and include additional state requirements for circumstances unique to a state.

The purpose of the CSA is "to improve the manufacturing, importation and exportation, distribution, and dispensing of controlled substances and to prevent the diversion, and the illegal misuse, of controlled substances. Entities involved in the manufacture, distribution, and dispensing of controlled substances must register with the DEA. Registration of these entities with the DEA results in the formation of a closed and comprehensive system for controlled substances

[9] PDMP Center of Excellence, *Mandating PDMP participation by medical providers: current status and experience in selected states*, Brandeis University (Feb. 2014).

distribution. This closed system allows for controlled substances to be traced from initial manufacture to final dispensing to the patient."[10] Every entity, registrant, and agent of a registrant in the supply chain bears responsibility for preventing the misuse of controlled substances and diversion.

Maintaining a closed system for controlled substances which provide effective controls to guard against misuse and diversion is a vital public health concern. Prescription opioid medications are recognized as posing a high degree of risk from abuse and diversion.[11] As the last line of defense, pharmacies and pharmacists must ensure that prescriptions for controlled substances are issued for legitimate medical purposes, within the scope of the prescriber's practice, and not being abused or diverted. Corporate Chain Pharmacies exert tremendous control over policies and procedures at their stores and have an obligation to ensure their operation of stores and management of pharmacy employees supports their agents in maintaining effective controls to guard against diversion. Failure to exercise this responsibility places dangerous drugs outside of the closed system mandated by the CSA and state requirements, with the risk of significant harm and death.

C. Schedules of Controlled Substances

Under the CSA, drugs, substances, and certain chemicals used to make drugs are classified into five (5) distinct categories or schedules depending upon the drug's accepted medical use and the drug's abuse or dependency potential. The abuse rate is a determinate factor in the scheduling of the drug; for example, Schedule I drugs have a high potential for abuse and the potential to create severe psychological and/or physical dependence. As the drug schedule changes – Schedule II, Schedule III, etc., so does the abuse potential – Schedule V drugs represent the least potential for abuse. *See* 21 C.F.R. Sections 1308.11 through 1308.15.

Schedule I

Schedule I drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse. Some examples of Schedule I drugs are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote.

Schedule II

Schedule II drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous. Some examples of Schedule II drugs are: combination products with less

[10] *See also* 21 U.S.C. § 801(2).

[11] Rachel N. Lipari & Arthur Hughes, *How People Obtain the Prescription Pain Relievers They Misuse*, CBHSQ Report, National Survey on Drug Use and Health (Jan. 12, 2017).

than 15 milligrams of hydrocodone per dosage unit (Vicodin[12]), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin.

Schedule III
Schedule III drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Some examples of Schedule III drugs are: products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, testosterone.

Schedule IV
Schedule IV drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence. Some examples of Schedule IV drugs are: Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol.

Schedule V
Schedule V drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes. Some examples of Schedule V drugs are: cough preparations with less than 200 milligrams of codeine or per 100 milliliters Robitussin AC, Lomotil, Lyrica, Parepectolin.[13]

D. Registrant Requirements

Federal and state regulations clearly define the requirements for DEA registrants within the closed distribution system established by the CSA. A DEA registrant and its agents are wholly responsible for requirements of the CSA and state and federal requirements for controlled substances. Under the CSA and state regulations, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances."[14]

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[12] US Department of Health and Human Services (HHS) on December 16, 2013, submitted to the Administrator of the DEA its scientific and medical evaluation entitled, "Basis for the Recommendation to Place Hydrocodone Combination Products in Schedule II of the Controlled Substances Act." Pursuant to 21 U.S.C. 811(b), this document contained an eight-factor analysis of the abuse potential of HCPs, along with the HHS's recommendation to control HCPs in schedule II of the CSA. Effective October 6, 2014, the Administrator of the DEA rescheduled hydrocodone combination products from schedule III to schedule II of the Controlled Substances Act. Federal Register Volume 79, Number 163 (Friday, August 22, 2014)], [Rules and Regulations], [Pages 49661-49682], From the Federal Register Online via the Government Printing Office [www.gpo.gov], [FR Doc No: 2014-19922].

[13] *Id*.

[14] *See* 21 C.F.R. § 1301.71(a).; Another aspect of the requirement is that "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft." 21 C.F.R. § 1301.76(b) and local law

The CSA creates a "closed system" of distribution in which distribution may lawfully occur only among registered handlers of controlled substances, referred to as "registrants."[15] Former DEA deputy assistant administrator for the DEA office of diversion control diversion Joe Rannazzisi, testified that all DEA registrants have an obligation to provide effective controls to guard against diversion of controlled substances.[16]

All DEA pharmacy registrants are also required to maintain complete and accurate inventories and records of all regulated transactions involving controlled substances and listed chemicals, as well as provide adequate security controls to prevent their diversion. The closed system created and mandated by the CSA ensures that controlled substances are under the control of a DEA-registered Person until they reach the patient or are destroyed, and the CSA's regulatory requirements "ensure that all controlled substances are accounted for from their creation until their dispensing or destruction." *See* DEA, Definition and Registration of Reverse Distributors, 70 Fed. Reg. 22591 (May 2, 2005).

Compliance obligations for DEA registrants, pharmacies and their agents, focus on critical areas of practice such as inventory, security, record-keeping, prescription management and fraud monitoring, ordering, and dispensing / diversion prevention. Guidance issued by and actions taken by the DEA identified the aforementioned critical areas and provided clarification of the design and implementation of effective controls and compliance programs.

Examples include but are not limited to:

- Procedures to identify the common signs associated with the diversion of controlled substances;
- Routine and periodic training of all pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA;
- A System to notify the local DEA office of a refusal to fill a prescription for controlled substances where such refusal is based on the pharmacist's determination that the prescription was forged, altered, and/or issued for other than a legitimate medical purpose by a practitioner acting outside the usual course of professional practice;
- Policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations;

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enforcement; Even those in senior positions, particularly Kroger, have had trouble adhering to this basic requirement. See Jun. 14, 2023, Eric Griffin, 30(b)(6), Deposition (hereafter "Griffin Dep."), 117:10-24, 118:25-119:14; Griffin Dep. Ex. 13, WVMLP-3P000002035; Griffin Dep. Ex. 15, OBOP_0036867; Kroger Names Colleen Lindholz President of Pharmacy and The Little Clinic, https://ir.kroger.com/CorporateProfile/press-releases/press-release/2017/Kroger-Names-Colleen-Lindholz-President-of-Pharmacy-and-The-Little-Clinic/default.aspx.

[15] *See* DEA, 75 Fed. Reg. 16235, 16237 (Mar. 31, 2010).

[16] May 15, 2019, Joe Rannazzisi Deposition (hereafter "Rannazzisi II Dep."), 410:8-15.

- Not knowingly dispensing an invalid prescription or a prescription that the pharmacist reasonably believes was issued for other than a legitimate medical purpose or by a practitioner acting outside the usual course of professional practice;
- A System to provide reports of dispensing upon request;
- A System to assess the data and other information available to the pharmacy and to notify dispensing pharmacists of potentially suspicious prescribers and prescriptions;
- A System to identify and prevent early fills of Schedule II controlled substances and to fill only Schedules III-V controlled substances that are valid and appropriately authorized.

Within the usual and customary practice of pharmacy, the CSA provides that a pharmacist must carefully evaluate every prescription for a controlled substance presented for dispensing. The evaluation requires a determination whether the prescription is valid, and the validity of a prescription for a controlled substance must be determined before dispensing. The determination requires the pharmacist to ascertain that (i) the prescription was issued by a medical practitioner adhering to the usual course of his or her professional practice, (ii) the prescription is for a legitimate medical purpose, (iii) any red flag(s) has been identified and resolved, (iv) there is a bona-fide relationship between the prescriber and patient, and (v) the possibility of abuse, diversion, or fraud has been investigated and addressed.

E. Corresponding Responsibility

A primary tenet of the standard of care in the practice of pharmacy is a pharmacist's independent responsibility to ensure that all prescriptions are issued for a legitimate medical purpose by a practitioner authorized by law while acting in the usual course of his professional practice. This duty is also set forth in the CSA and state practice acts and rules. The regulations expressly define and outline the corresponding responsibility of a pharmacist dispensing controlled substances.

The CSA (21 C.F.R. § 1306.04), and as confirmed by additional guidance documents issued by the DEA, "The practitioner is responsible for the proper prescribing and dispensing of controlled substances. The pharmacist also has a corresponding responsibility regarding the dispensing of a prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA." Pharmacies are DEA registered corporations and must comply with obligations imposed by the CSA.[17] One obligation prohibits the issuance of an invalid prescription, and any "person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances."[18] This applies to pharmacists and pharmacies, because a "person" under the CSA "includes any individual, corporation."[19] "When prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid

[17] 21 U.S.C. § 822(b), § 823(f).
[18] 21 C.F.R. 1306.04(a).
[19] *See* 21 C.F.R. §§ 1300.01, 1306.02.

positive knowledge of the real purpose of the prescription."[20] "The corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself."[21]

When dispensing controlled substances, a pharmacist must follow the "usual course of professional practice."[22] As the Department of Justice's recent lawsuit against Walmart alleges, "for a pharmacist to comply with the limited dispensing authorization provided in 21 U.S.C. § 829, the pharmacist must dispense the controlled substances in the usual 'course of professional practice.'" Amended Complaint, *United States of America v. Walmart Inc.*, 1:20-cv-01744, Doc. No. 75 (D. Del. Oct. 7, 2022) at ¶ 67. This statutory limitation was adopted by the CSA under 21 C.F.R. § 1306.06. The obligations to "identify red flags, to resolve them before filing the prescription, and to document any resolution of red flags are recognized procedural responsibilities of pharmacists in the professional practice of pharmacy [and] a pharmacist who fails to fulfill them when dispensing controlled substances does not adhere to the usual course of his or her professional pharmacy practice as required by 21 U.S.C. § 829 and 21 C.F.R. § 1306.06."." *Id*. at ¶ 76. Former DEA deputy assistant administrator for the DEA office of diversion control diversion Joe Rannazzisi confirmed this in his testimony.[23] "[A] pharmacist who fails to fulfill them when dispensing controlled substances does not adhere to the usual course of his or her professional pharmacy practice as required by 21 U.S.C. § 829 and 21 C.F.R. § 1306.06." Complaint at ¶ 76.

The CSA clearly places the duty to prevent diversion of controlled substances upon each person and entity involved in the closed system. The CSA and its implementing regulations hold accountable the registrant, manufacturer, distributor, pharmacy, and pharmacist who ultimately dispensed the prescription. Importantly, the corresponding responsibility is a shared responsibility of the pharmacy and pharmacist and not the pharmacist alone.[24] Pharmacies have an important and crucial role in creating systems and programs to identify and prevent the filling of controlled substance prescriptions issued by prescribers for reasons such as not being appropriately licensed, and licenses expired or suspended. The pharmacy also has an important duty to create a system to identify critical components of the evaluation process, such as the prescriber's specialty and his scope of practice and the prescriber's prescribing patterns, in order for the prescription to be evaluated and determined whether the prescription is valid and written within the usual course of the prescriber's practice and for a legitimate medical purpose. The pharmacy has data that the pharmacist does not have access to, which should be used to identify red flags that are indicia of potential diversion and to share that information with the pharmacies' agents and employees. The pharmacy has an obligation to provide clear guidance through policies, procedures and training

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[20] Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy, 55 FR 4729, 4730 (1990).
[21] Top RX Pharmacy; Decision and Order, 78 FR 26069-01 (2013).
[22] 21 U.S.C. § 829.
[23] Apr. 25, 2019, Joe Rannazzisi Deposition (hereafter "Rannazzisi I Dep."), 196:1-16.
[24] *Holiday CVS, LLC, d/b/a/ CVS Pharmacy Nos. 219 and 5195*, Decision and Order, Fed Reg. Vol. 77, No. 198, p. 62316-62346, at 62341 (October 12, 2012) ("*Holiday CVS*").

relating to corresponding responsibility and to create systems and programs to monitor the pharmacy to ensure that the policies, procedures, and training are being followed.[25]

"The corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself."[26] The *Holiday* decision was not the first DEA decision to hold pharmacies responsible for failing to fulfill their corresponding responsibility under the CSA; similar opinions were issued in *Medicine Shoppe-Jonesborough* and *United Prescription Services, Inc.*[27] The DEA has consistently held the pharmacy corporation, including Defendants in related litigation, responsible for failing to exercise its corresponding responsibility under the CSA.

Corresponding responsibility is also identified and defined in the DEA's publication—The Pharmacist's Manual An Informational Outline of the Controlled Substances Act and Actions (administrative and criminal) - Revised 2010.

> SECTION IX – VALID PRESCRIPTION REQUIREMENTS To dispense controlled substances, a pharmacist must know the requirements for a valid prescription which are described in this section. A prescription is an order for medication which is dispensed to or for an ultimate user.
>
> Corresponding Responsibility
>
> A pharmacist also needs to know there is a **corresponding responsibility** for the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA (21 U.S.C. § 829). The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.
>
> A pharmacist is required to **exercise sound professional judgment** when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law **does not** require a pharmacist to dispense a prescription of **doubtful, questionable, or suspicious origin**. To the contrary, the pharmacist who deliberately ignores a questionable prescription when **there is reason to believe it was not issued for a legitimate medical** purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. Such action is a felony offense, which may result in the loss of one's business or professional

[25] *See* Rannazzisi II Dep., 436:10-437:25 (Mr. Rannazzisi further explained that pharmacies are a part of the closed system and have a "legal obligation to follow the security and recordkeeping requirements" to comply with the CSA regulations).
[26] *Holiday CVS*; Fed Reg. Vol. 77, No. 198, at 62341.
[27] 73 FR 364, 384 (2008); 72 FR 50397, 50407-08 (2007).

> license (*see United States v. Kershman*, 555 F.2d 198 (8th Cir. 1977) (emphasis added).

The CSA and state laws inform the pharmacist that he is not required to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who fills a prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances.

A pharmacist who "filled a prescription notwithstanding her actual knowledge that the prescription lacked a legitimate medical purpose" or who "was willfully blind or deliberately ignorant to the fact that the prescription lacked a legitimate medical purpose" violates the corresponding responsibility requirement. *Pharmacy Doctors Enterprises*, 83 Fed. Reg. 10,876, 10,896 (DEA Mar. 13, 2018).

A pharmacist was found to have illegally dispensed controlled substances when the pharmacist "deliberately closed his eyes to the true nature of the prescription." *United States v. Lawson*, 682 F.2d at 482.

"Red Flags"

A pharmacist's corresponding responsibility and determination of whether a prescription issued for a controlled substance is valid and legitimate, requires systems and actions to recognize, investigate, and resolve signs of a prescription's invalidity (red flags) "arising during the presentation of a prescription which creates a reasonable suspicion that the prescription is not, on its face, legitimate."[28] Red flags are warning signs and can also indicate activities are occurring outside the usual and customary scope of pharmacy practice, activities that are more than likely to include abuse, diversion, and fraudulent acts. According to Jamie McDermott, Kroger's Manager of Pharmacy Controlled Substance Compliance, red flags are "circumstances surrounding the presentation of a controlled substance prescription that does or should raise a reasonable suspicion as to the validity of a prescription."[29]

Red flags are not a novel or unknown concept to pharmacists, pharmacies, or Defendants. Red flags are common sense warning signs that have long been an important component of controlled substance pharmacy best practices. In addition, at least since the 1930s and 1940s there has been

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[28] *United States v. City Pharmacy, LLC*, No. 3:16-CV-24, 2017 WL 1405164, at *4 (N.D. W.Va. Apr. 19, 2017); *see also United States v. Lawso*n, 682 F.2d 480, 483 n.6 (4th Cir. 1982).

[29] Mar. 28, 2022, Jamie McDermott Deposition (hereafter "McDermott II Dep."), 152:20-153:15 -22; see also, P-KRO-0471 at KrogerMDL00002142, "Controlled Substance Compliance Current Trends & Reminders (September 2014).

guidance given to pharmacies and pharmacists related to the creation of systems and programs to guard against diversion and lists of "don'ts" when dispensing narcotics.[30]

Pharmacists have been trained when determining whether to fill a prescription for a controlled substance and to be alert for suspicious activities surrounding the prescription. Licensed or registered pharmacists in every state are required to complete a formal education program of didactic and practical experience.

Every state requires pharmacists, as part of their formal education, to complete a state law or jurisprudence examination to qualify for licensure or transfer an existing license. In 2010 and continuing to 2019, 48 states required NABP's Multistate Jurisprudence Examination (MPJE). A validation study of the MPJE conducted in 2010 determined that the application of pharmacy law within the practice of pharmacy required increased emphasis on pharmacy jurisprudence as it applies to the practice of pharmacy. The emphasis included corresponding responsibility and red flags.[31]

Red flags of diversion are known or should be known to pharmacies and pharmacists in the usual and customary practice of pharmacy. As noted above, red flags are known concepts in pharmacy practice and the regulation of pharmacy practice as well as the subject of DEA guidance, guidance from State Boards of Pharmacy, negotiated consensus documents published by the NABP, and by industry trade groups such as the National Association of Chain Pharmacies. Videos have also been created to give guidance to pharmacies and pharmacists on red flags of diversion.[32] Red Flags have also been the subject of numerous DEA diversion investigations, registration suspensions and revocations, and criminal and civil actions.

The performance of the red flag analysis required by the pharmacy's corresponding responsibility was especially critical when those in the practice of pharmacy became aware that opioid diversion and misuse had reached epidemic proportions.

Defendants, as distributors of controlled substances, were sent copies of DEA Deputy Assistant Administrator Joseph T. Rannazzisi's 2006 and 2007 letters describing distributors' obligations under the CSA with respect to suspicious order monitoring. In his first letter, dated September 27, 2006, Rannazzisi wrote,

> The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces. …

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[30] *See* Prescribing and Dispensing Narcotics Under the Harrison Narcotic Law, Pamphlet 56, U.S. Treasury Dep't, U.S. Bureau of Narcotics, (July 1938); Treasury Department, U.S. Bureau of Narcotics, late 1940s, "Narcotics 'DON'TS' for the Pharmacist," n.d., "Demerol," FBN Papers (IMG_3801).

[31] NABP MPJE Competency Statements 2016.

[32] "Red Flags," NABP Video produced by the Anti-Diversion Industry Working Group (May 20, 2014).

> As each of you is undoubtedly aware, the abuse (nonmedical use) of controlled prescription drugs is a serious and growing health problem in this country."[33]

As early as 2011, Publix's then Vice President of Pharmacy, Fred Ottolino, acknowledged in a memo to all pharmacists that "[p]rescription drug abuse is the nation's fastest growing drug problem."[34] Moreover, Publix has historically viewed the opioid epidemic as a "threat".[35] Kroger has been aware of the opioid problem in this country since at least the mid-2000s. In 2005, Kroger entered into a settlement with DEA regarding its compliance programs around controlled substances. The settlement involved Kroger's lax handling of controlled substances in its stores in Colorado.[36] Kroger paid a settlement of $7,000,000 and agreed to "implement a Comprehensive Regulatory Compliance Program," and to train all of its employees pursuant to the Compliance Program.[37] Kroger also received the letters from Rannazzisi in 2006 and 2007.[38]

In 2011, the CDC reported that:

> In 2007, nearly 100 persons per day died of drug overdoses in the United States. The death rate of 11.8 per 100,000 population in 2007 was roughly three times the rate in 1991. Prescription drugs have accounted for most of the increase in those death rates since 1999. In 2009, 1.2 million emergency department (ED) visits (an increase of 98.4% since 2004) were related to misuse or abuse of pharmaceuticals, compared with 1.0 million ED visits related to use of illicit drugs such as heroin and cocaine. Prominent among these prescription drug-related deaths and ED visits are opioid pain relievers (OPR), also known as narcotic or opioid analgesics, a class of drugs that includes oxycodone, methadone, and hydrocodone, among others. OPR now account for more overdose deaths than heroin and cocaine combined. OPR frequently are diverted for nonmedical use by patients or their friends or sold on the street. In 2010, 4.8% of the U.S. population aged ≥12 years used OPR nonmedically. Nonmedical use of OPR costs insurance companies up to $72.5 billion annually in health-care costs.[39]

According to the CDC, as of 2019, nearly 841,000 people have died since 1999 from a drug overdose. The number of drug overdose deaths increased by nearly 5% from 2018 to 2019 and had quadrupled since 1991. Over 70% of the 70,630 drug-related deaths in 2019 involved an opioid.

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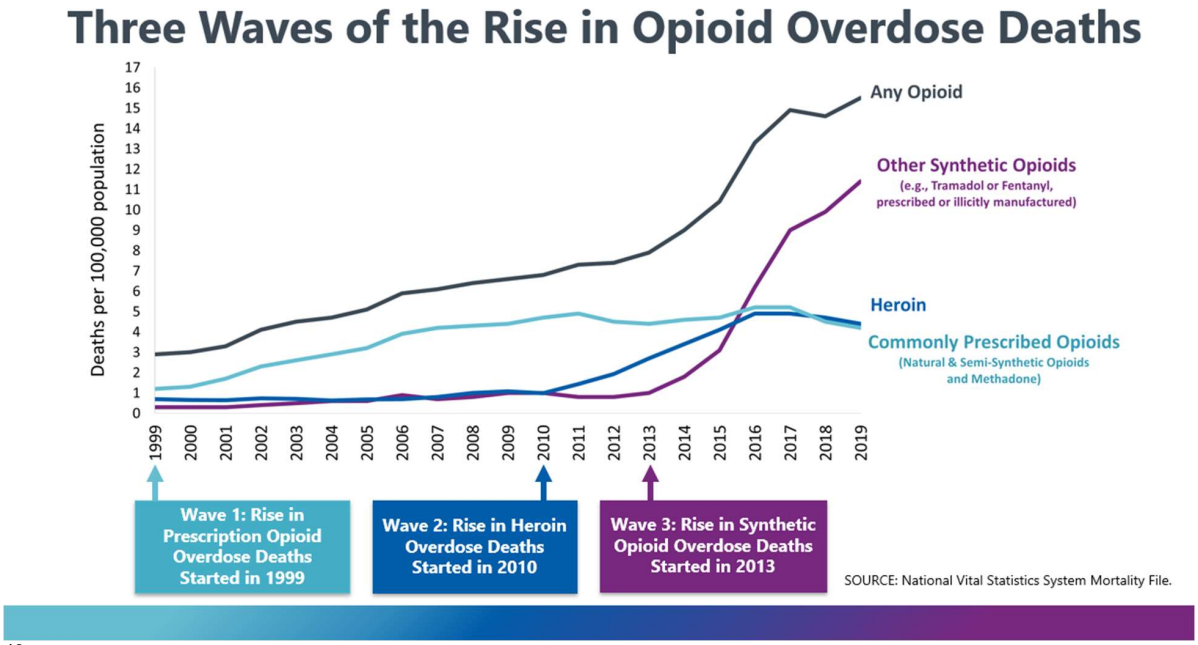
[33] CAH_MDL_PRIORPROD_DEA12_0006133 (Rannazzisi Ex. 12), citing National Institute on Drug Abuse Research Report: Prescription Drug Abuse and Addiction (revised August 2005): available at www.drugabuse.gov/PDF/RRPrescription.pdf. *See also* US-DEA-00022457 (2/7/2007); PUBLIX-MDLT8-00147285, P-PUB-0429 (12/27/2006) (Rannazzisi Ex. 13)
[34] PUBLIX-MDLT8-00118914 (Chavez Dep. Ex. 11; Ottolino Dep. Ex. 1).
[35] PUBLIX-MDLT8-00071826.
[36] US-DEA-00012570, P-32287_00023-54.
[37] Kroger-MDL00031079.
[38] KrogerSmithNMAG00003203.
[39] CDC, V*ital Signs: Overdoses of Prescription Opioid Pain Relievers --- United States, 1999-2008*, Weekly (Nov. 4, 2011).



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Thus, Defendants recognized the ongoing and growing prescription opioid epidemic beginning in the mid to late 2000s.[41] Their policies, procedures, and training materials began to contain lists red flags of diversion for controlled substances. However, while Defendants eventually recognized red flags in their policies, they were slow to do so, and such recognition occurred long after the misuse of opioids was well known and the opioid crisis had become an epidemic. Following the DEA investigations into other registrants, in November 2012 Kroger instructed pharmacies to educate "all pharmacy staff on known red flags of diversion."[42] Kroger had some warning signs for pharmacists dispensing controlled substances in its 2005 SOP, those warnings remained stagnant at Kroger until 2012.[43] Kroger did not use the term "red flag" or identify additional signs of diversion until the 2012 read and sign that was issued to pharmacists following

[40] Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. March 2021.
[41] KrogerWVAG00002342 (noting that "[o]pioid-related deaths began to rise after sharp increase in prescribing" in the 1990s). Nov. 8, 2022, Leigh Anne Jacobson Deposition (hereafter "Jacobson Dep."), 191:1-192:12 (Publix pharmacist was aware of opioid crisis since at least 2010); PUBLIX-MDLT8-00118914 (Vice President of Publix pharmacy operations, Fred Ottolino issued a 2011 memo to all stores indicating that "[p]rescription drug abuse is the nation's fastest-growing drug problem."); P-PUB-0471 (Jacobson Exhibit 8) (Cobb County news article indicating that over-the-counter drug abuse jumped 15 percent from 2008 until 2009.
[42] KrogerMDL00001531.
[43] KrogerSmithNMAG00003033 at 00003090 (2005); KrogerSmithNMAG000348.

DEA investigations.[44] Nevertheless, Kroger's 2016 SOP still contained the same warning signs for pharmacists as the 2005 SOP[45] There was not consistent guidance through Kroger's policies. Further, Kroger should have updated its policies and procedures as diversion trends continued to evolve. Publix recognized the importance of regulations around controls for controlled substance prescriptions, but characterized these safeguards as "important for society, but a burden" for the retailer and distributer.[46] Guidance on red flags was not issued to Publix pharmacists until 2012 although it is unclear whether or not Publix pharmacists are even aware of such guidance.[47]

Walgreens and Walmart entered into Memoranda of Understanding or Agreement with the DEA and DOJ arising from DEA enforcement actions based upon their failure to identify and resolve these red flags of diversion in 2009-2011. CVS developed its first guidelines to pharmacists regarding warning signs of diversion only after receiving a direct warning from the DEA around the same time, later resulting in the *Holiday* decision and suspension of CVS's license.

Evidence that the abuse of opioids was well known and should have been known by the Defendants extends beyond the reports issued by the CDC, the DEA, and other credible government sources. In the face of the overwhelming evidence concerning the abuse of prescription opioid medications, the Defendants failed to address the presence of the opioid prescription epidemic in their pharmacies and failed to acknowledge the significance of red flag analysis as a critical component to prevent opioid drug diversion.

In *Jones Total Health Care Pharmacy, L.L.C., and SND Health Care, L.L.C.*; Decision and Order,[48] the DEA noted that an administrative law judge had "specifically rejected" the argument that a pharmacy owner, whose charged conduct occurred in the 2010-2012 time-frame, **"**was simply naïve or unaware of various indicia (otherwise known as red flags) that the prescriptions her pharmacy filled lacked a legitimate medical purpose as well as its contention that during the relevant time period," and credited testimony that, in "2010, Florida pharmacists were generally aware of various red flags of abuse and diversion." The decision also notes that, although an expert had "testified that the first reference to the term 'red flag' that she could find in DEA's public pronouncements was in the Holiday CVS decision," that was incorrect, as "the term appears in DEA administrative decisions involving practitioners including pharmacies" earlier than that, as well as "federal court decisions that predate 2010." *Id.* at Note 23 (citing *Paul J. Caragine*, 63

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[44] KrogerSmithNMAG000348.
[45] Feb. 22, 2022, Jamie McDermott Deposition (hereafter "McDermott I Dep."), 303:21-304:2; KrogerMDL00000329 at 00000399; KrogerSmithNMAG00003033 at 00003090.
[46] PUBLIX-MDLT8-00071828 (P-PUB-0324). As late as 2018, Publix viewed the opioid epidemic as a "threat" and acknowledged that it needed to respond to the opioid epidemic "with better tools to ensure we are efficiently meeting requirements yet taking care of the customer." *Id.*
[47] PUBLIX-MDLT8-00002439 at 00002475. Publix pharmacist Shannon Brice testified that despite working as a Publix pharmacist for 25 years and a Cobb County pharmacy manager responsible for overseeing and training other pharmacists, she had not previously seen or reviewed the 2012 policy until just weeks before her deposition. See Aug. 3, 2023, Shannon Brice Deposition (hereafter "Brice Dep.").
[48] *Jones Total Health Care Pharmacy, LLC v. Drug Enf't Admin.,* 881 F.3d 823 (11th Cir. 2018), available at https://www.deadiversion.usdoj.gov/fed_regs/actions/2016/fr1110_3.htm.

F.R. 51592, 51600 (1998); *Medicine Shoppe-Jonesborough*, 73 F.R. 364 (2008); *United Prescription Services, Inc*., 72 F.R. 50397 (2007); *Medicine Shoppe- Jonesborough v. DEA*, 300 Fed. Appx. 409, 413 (6th Cir. 2008); *United States v. Alerre*, 430 F.3d 681, 686 (4th Cir. 2005); *United States v. Chin*, 795 F.2d 496, 502 (5th Cir. 1986)).

The same agency decision notes that "[i]n any event, the term 'red flag' has been part of the lexicon for more than 200 years, and whether the Agency has used this term, or such terms as 'warning signs' or 'suspicious circumstances,' is of no consequence." *Id.* (explaining that "[w]hat matters is whether Respondent's pharmacists either knew or were willfully blind to the fact that the controlled substance prescriptions they dispensed lacked a legitimate medical purpose"). As a matter of pharmacy practice, it is my opinion that a pharmacy chain could and should have used the data available to them, including but not limited to their own dispensing data, to assist their pharmacist and pharmacies in detecting and addressing red flags for diversion. *See* Section D. above.

What follows is a list and description of certain red flags of diversion that were able to be captured in the Defendants' dispensing data produced in this litigation.

Red flags of diversion can generally be categorized as Prescriber Red Flags, Patient Red Flags, Prescription Red Flags and Pharmacy Red flags.

Defendants produced dispensing data from the pharmacies they operated in Georgia. A number of red flags can be identified using the fields produced in the dispensing data. I have requested that Craig McCann and SLCG calculate the number of opioid prescriptions triggered by the red flags described in this report. I have also reviewed and relied upon Dr. McCann's expert report and appendices submitted in this litigation, which contains analysis of red flag prescriptions. Below is a description of these red flags:

Patients traveling long distances to fill opioid prescriptions

1. Pharmacy Distance- Patient generally travels over 25 miles to pharmacy.
2. Prescriber Distance- Patient generally travels over 25 miles to prescriber.

In the usual and customary practice of pharmacy, patients ordinarily frequent pharmacies that are convenient to their lifestyles. That convenience translates into using a pharmacy that is close to their residence or place of employment. Exceptions can occur when the individual's drug coverage under their insurance plan mandates certain pharmacies, the pharmacy that they frequent is out of a medication, or the patient is being treated by practitioners at a tertiary care facility that is highly specialized to provide services such areas as cardiac surgery, cancer treatment and management, burn treatment, plastic surgery, neurosurgery and other complicated treatments or procedures. Further, according, to the CDC, nearly nine out of ten Americans live within five miles of a

community pharmacy.[49] An earlier study stated that "more than 90% of Americans live within 2-miles to one of these pharmacies."[50] A patient that travels an inordinate distance (greater than 25 miles) to a particular pharmacy to obtain controlled substances is a recognized red flag that should be known to a pharmacist.[51] The use of 25 miles as a reference point is based upon standards used by states in establishing and permitting telepharmacies. In 2003, the North Dakota Board of Pharmacy was the first state to establish permanent rules allowing telepharmacy. North Dakota and other states utilized 25 miles or greater as one of the determinants for defining a telepharmacy in medically underserved remote rural communities. Based upon my review and considering the extensive diversion of opioids in Georgia, I believe 25 miles is an appropriate guideline. The distance flags are defined as follows:

- The incidence of prescriptions for Pharmacy Distance - An opioid was dispensed to a patient who traveled more than 25 miles to visit the pharmacy. The distance here is calculated from the center of the patient's zip code to the center of the pharmacy's zip code.

- The incidence of prescriptions for Prescriber Distance - An opioid was dispensed to a patient who traveled more than 25 miles to visit their prescriber. The distance here is calculated from the center of the patient's zip code to the center of prescriber's zip code.

Chain Pharmacies' policies and internal documents, albeit promulgated after an unreasonable delay in time, recognize that an inappropriate distance traveled between a patient and a prescriber and a patient and a pharmacy is a red flag of diversion.

> Kroger: "Patient has driven a long distance to see a doctor,"[52] "Patient that isn't a usual customer or doesn't live in the community around the pharmacy or prescriber (patient travels over > 100 miles to see the physician)"[53]
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> Publix: "The prescriber's practice is not near where the patient resides."[54]

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[49] CDC, Get to Know Your Pharmacist, https://www.cdc.gov/heartdisease/pharmacist.htm.
[50] Dima Qato, Shannon Zenk, Jocelyn Wilder, Rachel Harrington, Darrell Gaskin, & G. Caleb Alexander, *The availability of pharmacies in the United States: 2007–2015,* PLoS One 2017;12(8), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5559230/#pone.0183172.ref002.
[51] In the *Holiday CVS* administrative action, a patient travelling a long distance to fill prescriptions was noted as a red flag and "indicator of possible diversion"). In *Pharmacy Doctors Enterprises, Inc*., *v. Drug Enf't Admin.*, 789 Fed. Appx. 724, 730 (11th Cir. 2019), customers traveling "hundreds of miles roundtrip" was again noted as a red flag. Finally, in *East Main Street Pharmacy*, patients "driving long distances to have their prescriptions filled" was demarcated as a red flag and particularly, the "pattern of patients traveling long distances from the location of their home and physician is extremely unusual and very suspicious." *East Main Street Pharmacy,* Affirmance of Suspension Order, 75 F.R. 66149-01 (October 27, 2010) ("*East Main Street Pharmacy*").
[52] KrogerSmithNMAG000348.
[53] KrogerMDL00002122 at 2144/ P-KRO-0471.
[54] PUBLIX-MDLT8-00002439 at 00002475.

Walmart: Prescriber or individual is "outside of the pharmacy's trade area."[55]

CVS: "[E]ither or both the patient and prescriber not being located within the store's geographic areas (in most cases)."[56] CVS Prescriber Algorithm Metrics and Definitions: Relative Distance is defined as: "Patients who travel more than 20 miles to the pharmacy based on the centroid of the respective zip codes."[57]

Walgreens: "Unusual geographical distances between patient, pharmacist, and prescriber"[58]). "Individual resides outside of the trade area of your pharmacy, prescription is written by a prescriber located outside of the pharmacy's trade area."[59] In 2021, Walgreens piloted a notification function that alerts pharmacists when the distance threshold is exceeded.[60] This threshold is calculated using triangular data points that include the zip codes of the pharmacist, patient, and prescriber.[61] In urban areas, the triangular perimeter is set to 30 miles.[62]

Rite Aid: "The patient or the prescriber is located outside the pharmacy's typical geographic area (e.g., patient's address is OH, prescriber's address is FL, and your pharmacy is located in KY)."[63]

Further, in 2015, a coalition of stakeholder organizations and the trade organization for the chain drug stores, of which Kroger and Publix were members, the National Association of Chain Drug Stores ("NACDS")[64]among others, along with the NABP released a consensus document ("NABP Stakeholder Report") on the challenges and "red flag" warning signs related to prescribing and dispensing controlled substance prescriptions."[65] The NABP Stakeholder Report also recognized as a red flag patients "traveling unexplainable and/or unreasonably long distance to a physician office and/or the pharmacy" (long distance).[66]

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[55] WMT_MDL_000042957 at 42958. (POM 1311 (2015)); *see also* WMT_MDL_000069117 (POM 1311 (2011)) ("the prescription was written by an out-of-state prescriber").
[56] CVS-DR22-000001039.
[57] CVS-MDLT3-000034325.0011
[58] WAGMDL00093367 Good Faith Practices (Revised 08/01/98).
[59] WAGMDL00256710, April 2013 Presentation, Pharmacist GFD Review Coaching Opportunities.
[60] Feb. 11, 2021, Jon Arends Deposition, 132-134.
[61] *Id.*
[62] *Id.*
[63] Rite_Aid_OMDL_0044309, #RXO00037-2012 – Procedures for Validation and Dispensing of High Alert Controlled Substances.
[64] Kroger, Publix, Walmart, Meijer, Walgreens and, until July of 2022, CVS were members of NACDS, among others.
[65] WAGMDL00502238, Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances.
[66] *Id.*; *see also* NABP_00022121, Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances.

In 2013, NACDS included as a red flag instances where "[p]atient travels long distance to physician and/or pharmacy."[67] Kroger and Publix were both members of NACDS at the time that guidance was issued.[68]

Doctor Shopping:

Doctor shopping, as a red flag, includes when a patient presents a prescription for a controlled substance and may be obtaining the same or similar controlled substance from a different prescriber(s) and the patient does not make the prescriber aware of the other prescriber.[69] The red flag assists with the identification of individuals who are searching for a cooperative prescriber who will willingly prescribe the desired controlled substances.[70] The doctor shopping flag are calculated as follows:

> 3. A patient was dispensed opioid prescriptions with overlapping days of supply that were written by two or more prescribers.

It is worth noting that certain red flags which implicate multiple prescriptions, such as doctor shopping, may not be readily apparent to the pharmacist when the first prescription is presented. Nevertheless, once the second prescription is presented, the pharmacy must review and investigate both prescriptions because they are red flagged prescriptions.[71]

Pharmacy Shopping:

Pharmacy shopping occurs as a red flag when a patient travels to multiple pharmacies to fill controlled substances prescriptions with the intent moving from pharmacy to pharmacy in the hopes of getting multiple controlled substances without being detected. In the usual and customary practice of pharmacy, the overwhelming percentage of patients (>60%) use one pharmacy as their primary source of medications. Clinically, the overall health status appeared to be the worst for patients filling at multiple pharmacies concurrently and similarly, non-adherence higher.[72] The pharmacy shopping flag is:

> 4. Patient was dispensed opioid prescriptions with overlapping days of supply at two or more pharmacies.

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[67] WMT_MDL_000891159.
[68] FM 00028867 at 00028880; PUBLIX-MDLT8-00066956.
[69] Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances, WAGMDL00502238; WMT_MDL_000891159.
[70] *Id.*
[71] This same rationale applies to various flags including 4, 5, 7, 11 and 13.
[72] Zachary Marcum, Julia Driessen, Carolyn Thorpe, Walid Gellad, & Julie Donohue, *Impact of Multiple Pharmacy Use on Medication Adherence and Drug-drug Interactions in Older Adults with Medicare Part D.*, J Am Geriatr Soc. 2014 Feb; 62(2): 244–252.

Chain Pharmacies' policies and documents recognized, again long after the epidemic was in full swing, that doctor shopping and pharmacy shopping were red flags:

Kroger: Patient red flag includes "doctor shopping."[73]

Publix: "The patient changes prescribers frequently ('doctor shopping')."[74]

Walmart: Patient red flags include: "evidence of "doctor shopping" and "pharmacy shopping" (often tied with traveling long distances).[75]

CVS: "Doctor Shopping—Evidence of multiple doctors prescribing controlled prescriptions for customer…." [76] "Doctor shopping refers to the practice of an individual patient (who may or may not have legitimate medical issues) visiting multiple doctors in order to obtain multiple prescriptions for a controlled substance. The individual will typically have the multiple prescriptions filled at different pharmacies."[77]

Walgreens: "evidence" of "doctor shopping" and "pharmacy shopping" are red flags of diversion.[78]

Rite Aid: "multiple prescribers" and "multiple pharmacy locations" as a flag for all prescriptions."[79]

NABP Stakeholder Document: The NABP Stakeholder Report: "Patient presents a prescription for controlled substance that the pharmacist knows, or reasonably believes, that another pharmacy refused to fill."[80]

The NACDS DEA Subcommittee Draft: "Prescription drug abusers will often attempt to obtain controlled substances from multiple pharmacies during adjacent or overlapping periods of time."[81]

Drug cocktails (an opioid, a benzodiazepine, and a muscle relaxer dispensed concurrently, i.e., the "Holy Trinity"):

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[73] Kroger-MDL00018716 at 00018730.
[74] PUBLIX-MDLT8-00002439 at 00002475.
[75] POM 1311, Practice Compliance, Proper Prescriber-Patient Relationship/Corresponding Responsibility, WMT_MDL_000042957.
[76] CVS-MDLT3-000006234.
[77] CVS-NYAG-000030739.
[78] WAGMDL00021306.
[79] Rite_Aid_OMDL_0044327; Rite_Aid_OMDL_0058008; Rite_Aid_OMDL_0060444.
[80] Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances, WAGMDL00502238.
[81] CVS-MDLT3-00008617;

Combining drugs to achieve a desired clinical outcome, a cocktail, is an accepted means of therapy employed to treat patients diagnosed with complex conditions such as cancer or infection with the HIV virus. In these examples, the medical literature documents the effectiveness of the combinations and rationale for their use. Cocktails composed of drugs of abuse, such as opioids, lack any documented medical efficacy and, conversely, are well-documented in the literature because of the dangers posed to patients, propensity for addiction, the diversion of such drugs often because of the mimicking effects of illegal drugs such as heroin.

Combinations of certain drugs are called "Trinities." A Trinity is a broad term and can include different combinations of opioid/non-opioid prescriptions intended for abuse and to create a euphoric feeling similar to heroin and other illicit drugs.[82] The classic Trinity or "Holy Trinity" consists of an opioid, a benzodiazepine, and a muscle-relaxer such as carisoprodol.[83] These are also drugs that are frequently diverted. [84]

When combined, the three drugs produce enhanced euphoric effects beyond the effect of the individual drugs. Alarmingly, the combination of opioids and benzodiazepine in this Trinity combination also intensifies the risk of overdose and death. There is no legitimate medical purpose in prescribing or dispensing these medications together. The Holy Trinity flags are calculated as follows:

5. Patient was dispensed an opioid, a benzodiazepine, and a muscle relaxer for overlapping days of supply.

These concerns are heightened when the cocktail prescriptions were written by the same prescriber and filled by the pharmacy on the same day.

6. Patient was dispensed an opioid, a benzodiazepine and a muscle relaxer on the same day and all the prescriptions were written by the same prescriber.

Drug Cocktail (An opioid and benzodiazepine):

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[82] Complaint, *U.S. v. Walmart Inc.*, No. 11:20-cv-01744-CFC, p. 102 (D. Del. Dec. 22, 2020).

[83] The Holy Trinity drug cocktail has been described in DEA administrative decisions as early as 2008. *See Your Druggist Pharmacy*, 73 Fed. Reg. 75,774, 75,775 n.1 (DEA Dec. 2008) - "[w]hile carisoprodol [was] not controlled under Federal law, it is controlled under various state laws and is highly popular with drug abusers, especially when taken as part of a drug cocktail that includes an opiate and a benzodiazepine." In *U.S. v. Evans*, 892 F.3d 692, 706 (5th Cir. 2018), which arose out of charges based on conduct occurring between 2010 and 2012, it was noted that the combination of opioids, benzodiazepines, and a muscle relaxer such as carisoprodol is "a well-known and highly abused drug cocktail." This finding was also made in other actions including, but not limited to, *East Main Street Pharmacy* - "the combination of a benzodiazepine, a narcotic and carisoprodol is well known in the pharmacy profession as being used 'by patients abusing prescription drugs."; *Holiday CVS*, - citing drug cocktails issued by physician for oxycodone, benzodiazepines and carisoprodol and their abuse potential.

[84] Publix Pharmacy Operations Manager for the Atlanta Division (2004-2017), Rodney King testified that the Trinity (combination of opioids, benzodiazepines, and a muscle relaxer) would be looked at as "an example of suspicious activity". *See generally* Nov. 30, 2022, Rodney King Deposition (hereafter "King Dep."), 153:13-155:11.

The medical literature has shown increased risk of respiratory depression when taking an opioid with a benzodiazepine since at least 2002.[85] Medical literature has also detailed that "benzodiazepines… are used to enhance the euphoriant effects of opioids (such as to boost methadone doses) to alleviate withdrawal or abstinence syndromes…"[86] Pharmacy practice has recognized drug combinations which include opioids and benzodiazepines as being generally known as being diverted and popular with drug abusers by at least 2005.[87] In 2015, 23 percent of people who died of an opioid overdose also tested positive for benzodiazepines.[88] A study of over 300,000 continuously insured patients receiving opioid prescriptions between 2001 and 2013, found that people concurrently using both drugs were at higher risk of visiting the emergency department or being admitted to a hospital for a drug-related emergency. More than 30 percent of overdoses involving opioids also involve benzodiazepines. [89] Other studies highlighted the dangers of co-prescribing opioids and benzodiazepines. A cohort study in North Carolina found that the overdose death rate among patients receiving both types of medications was 10 times higher than among those only receiving opioids.[90]

In the usual and customary practice of pharmacy, the combination of an opioid and benzodiazepine, both CNS depressants, is dangerous and contraindicated because of the extenuated adverse effects of the drugs particularly sedation and suppression of breathing.[91] The

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[85] John Caplehorn & Olaf Drummer, *Fatal methadone toxicity: signs and circumstances, and the role of benzodiazepines*, Aust N Z Public Health, 2002 Aug: 26(4): 358-362.

[86] Lance Longo, Addiction: Part I. Benzodiazepines – side effects, abuse risk and alternatives Am Fam Physician, 2000; 61 (7) 2121-2128.

[87] *East Main Street Pharmacy*, 75 FR 66149, 66163 (October 27, 2010) (drug cocktails which include benzodiazepine, opioids, and muscle relaxers are widely known in pharmacy practice as being popular with drug abusers).

[88] Centers for Disease Control and Prevention (CDC, *Multiple Cause of Death, 1999-2015*, CDC WONDER Online (Apr. 4, 2017).

[89] Eric Sun, Anjali Dixit, Keith Humphreys, Beth Darnall, Laurence Baker & Sean Mackey, *Association between concurrent use of prescription opioids and benzodiazepines and overdose: retrospective analysis,* BMJ 2017;356: j760 (Jan. 30, 2017).

[90] Tae Woo Park, Richard Saitz, Dara Ganoczy, Mark Ilgen & Amy Bohnert, *Benzodiazepine prescribing patterns and deaths from drug overdose among US veterans receiving opioid analgesics: case-cohort study,* BMJ. 2015;350:h2698 (Apr. 15, 2015).

[91] John Caplehorn & Olaf Drummer, *Fatal methadone toxicity: signs and circumstances, and the role of benzodiazepines*, Aust N Z Public Health, 2002 Aug: 26(4): 358-362; Susanne Nielsen, Paul Dietze, Nicole Lee, Adrian Dunlop, & David Taylor, *Concurrent buprenorphine and benzodiazepines use and self-reported opioids toxicity in opioid substitution treatment,* Addiction 2007 Apr;102(4):616-22; Jermaine Jones, Shanthi Mogali, Sandra Comer, *Polydrug abuse: a review of opioid and benzodiazepine combination use,* Drug Alcohol Depend. 2012; 125(1-2):8-18.

suppression of breathing is the primary the cause of overdose fatality.[92,93] The DEA has also warned about the dangers of overdose, abuse and diversion.[94]

In a 2018 discussion on opioids, Dr. Patrice Harris, the former President of the American Medical Association, made clear that organization's position on patients who present with a prescription for both an opioid and a benzodiazepine stating, "that is a deadly, potentially, deadly combination." She went on to state that, at least in Georgia, "a lot of our overdose deaths were due to that combination."[95] The opioid and benzodiazepine flags are calculated as follows:

7. An opioid and a benzodiazepine were dispensed to a patient within 30 days of one another. These dangers and risks are highlighted when the opioid and benzo were dispensing together.

8. Patient was dispensed an opioid and a benzodiazepine on the same day and all the prescriptions were written by the same prescriber.

Drug Cocktail (Two short-acting opioids):

Immediate-release opioids (in contrast to extended-release or long-acting opioids) release the drugs more quickly into the bloodstream and generally have a shorter analgesic effect than extended-release drugs. Studies in the clinical literature report that immediate-release or short acting opioids are more likely to lead to more abuse and aberrant behavior then long-acting opioids because of the pharmacokinetic and pharmacodynamic features of the immediate release products.[96] Pharmacists would recognize an obvious red flag when multiple prescriptions for immediate release opioids were presented at the same time or sufficiently close in time that the drugs would have overlapped.

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[92] Debra Dowell, Tamara Haegerich, Roger Chou, CDC *Guideline for Prescribing Opioids for Chronic Pain — United States, 2016,* Morbidity and Mortality Weekly Reports (Mar. 18, 2016).

[93] Food and Drug Administration, Safety Announcement, "FDA Warns about Serious Risks and Death When Combining Opioid Pain or Cough Medicines with Benzodiazepines; Requires Its Strongest Warning" (August 31, 2016).

[94] In *Pharmacy Doctors Enterprises d/b/a Zion Clinic Pharmacy*, the show cause order issued on February 23, 2015 listed red flags of diversion that Zion Clinic allegedly did not resolve prior to filling prescriptions. One of the red flags noted was the dispensing of an "opiate (hydromorphone) and benzodiazepine (alprazolam, clonazepam, diazepam, or lorazepam)." 83 Fed. Reg. 10,876 at 10,877. The decision noted further that this drug cocktail was popular with drug abusers. *Id*. Similarly, in *Jones Total Health Care Pharmacy, LLC v. DEA*, 881 F.3d 823 (11th Cir. 2018), red flags were defined and included drug cocktails "known for their abuse potential, such as oxycodone and a benzodiazepine." Accordingly, comparable determinations were made in *Holiday CVS* - the combination of an opioid and benzodiazepine like alprazolam "are commonly diverted to nonmedical use"; *East Main Street Pharmacy*.

[95] The Augusta Chronicle, "Dr. Patrice Harris Talks About Opioids," Aug. 12, 2018 https://www.youtube.com/watch?v=kbToYDmh16M.

[96] Laxmaiah Manchikanti, Rajeev Manchukonda, Vidyasagar Pampati, & Kim S Damron, *Evaluation of abuse of prescription and illicit drugs in chronic pain patients receiving short-acting (hydrocodone) or long-acting (methadone) opioids,* Pain Physician 2005;8(3):257-261.

There has been some debate among professionals concerning whether methadone should be treated as a short acting or long acting opioid. Methadone is inherently dangerous given the length of time the substance remains in the human body. As a result, methadone—while a short acting opioid—also has propensity to act similar to a long acting opioid. For this reason I have, to be conservative, left it out of the analysis of two short acting opioids. The two short opioid flag is calculated as follows:

9. Patient was dispensed two short acting opioid drugs on the same day.

Chain Pharmacies' policies, the Stakeholders report, and NACDS recognize dangerous drug combinations as red flags:

> Kroger: "The prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Drug abusers often request prescriptions for "uppers and downers" at the same time."[97] Kroger identified the "Trinity cocktail: opioid, carisoprodol, benzo" as a red flag.[98]
>
> Publix: A 2021 policy required that patients are offered Narcan when dispensing a prescription for "opioids AND benzodiazepine[s] (regardless of MME))."[99]
>
> Walmart: POM 1311 (2015): "Prescriptions presented represent a 'cocktail' of commonly abused drugs or are presented in a combination that can cause medical complications."[100] Walmart only specified in 2017 that "cocktail" included "an opioid, a benzodiazepine, and a muscle relaxant . . . often referred to as the 'Trinity' or 'holy Trinity'" and added "[p]rescriptions for drugs with opposite effects (e.g., stimulants and depressants)" and "prescription for drugs with similar effects (e.g., multiple long acting or multiple short acting opioids)" as additional red flags.
>
> CVS: "Prescribes combinations the DEA has identified as having a high potential for abuse (e.g., oxycodone, alprazolam and carisoprodol)."[101]
>
> Walgreens: "Prescriptions presented represent a cocktail of commonly abused drugs."[102] In addition, on June 7, 2012, Walgreen's "Controlled Substance Action Plan" created an "Enhanced Drug Utilization Review" which provides:
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> "A DUR enhancement has been made to alert pharmacists to review a patient's profile and utilize Good Faith Dispensing procedures when dispensing select controlled substances.

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[97] KrogerSmithNMAG000348.
[98] KrogerMDL00002122 at 00002146.
[99] PUBLIX-MDLT8-00149649 at 00149653(P-PUB-0728) (Leonard Ex. 10).
[100] WMT_MDL_000042957.
[101] ROPP 047561 – Federal Guidelines for Controlled Substances, CVS-DR22-000001011.
[102] April 2013 training guide WAGMDL00054501.

- A Major DUR will flag when a patient has been prescribed medications, that in combination, have a high potential for abuse."
- The following message will appear to the pharmacist: "A strong association appears to exist between illicit use of Carisoprodol in combination with narcotic analgesics such as oxycodone and benzodiazepines such as alprazolam. . .."[103]

Rite Aid: Rite Aid did not list dangerous drug combinations—including the "Trinity"—as a red flag at all. These combinations were simply one type of "high alert controlled substance medications" that were then subject to the procedures for validation and dispensing of high alert controlled substances (the same as a prescription for oxycodone alone).[104] The only red flags which specifically mention dangerous drug combinations are (1) where "the prescriber routinely prescribes the same 'cocktail' or combination of drugs for pain treatment to most or all of his/her patients, particularly where DEA and other authorities have identified the combination as potentially abused (e.g. oxycodone, alprazolam and carisoprodol or any combination of drugs from these three drug classes" and (2) review of patient's profiles shows "only prescriptions for controlled substances in profile, or only fills for a combination of products commonly known as the 'Trinity' (oxycodone, alprazolam and carisoprodol or any combination of drugs from these three drug classes)."[105] Only in June 2017 did Rite Aid instruct pharmacists "when performing the NexGen red flag process for High-Risk Medications, be vigilant for prescriptions for 'The Trinity.'"[106]

NABP Stakeholders Document: (1) "therapeutic duplication of two or more long-acting and/or two or more short-acting opiates (cocktails); and (2) patient presents prescriptions for highly abused "cocktails" (combination of opiate, benzodiazepine, and muscle relaxant) of controlled substance medications (cocktails).[107]

NACDS: includes "prescribing questionable 'cocktails' of commonly diverted drugs" and "prescribing combinations of drugs that can cause medical complications" as red flags.[108]

Excessive Dispensing

Pharmacies and pharmacists engaged in the usual and customary practice of pharmacy, at the time in question, were aware of, or should have known, that opioids prescribed at any dosage presented a risk to the patient. The risk to the patient should be evaluated in order to consider the individual patient benefits and risks. A retroactive 2017 study by the Centers for Disease Control (CDC

[103] June 7, 2012 "Controlled Substance Action Plan", WAGMDL00742642.
[104] Rite_Aid_OMDL_0059009.
[105] *Id.*
[106] Rite_Aid_OMDL_0044309.
[107] Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances, NABP_00022121.
[108] NABP_00019878.

analyzed opioid prescribing at the national level from 2006-2015 and defined high dose prescribing rates to include prescriptions with daily dosage equal to or greater than 90 MME. Other studies examining the use of opioids and associated patient risks published in 2010 and 2011 demonstrated that the risk of overdose progressively increased at prescribed opioid dosages exceeding 20, 50, and 100 MME per day[109,110,111] and detected causal associations of prescribed opioids with overdose deaths.[112,113]

Additionally, a manuscript published in the Journal of the American Medical Association (JAMA) in 2016 discussing the CDC Guideline for Prescribing Opioids for Chronic Pain—United States, reported that "opioid-related overdose risk was dose-dependent, with higher opioid dosages associated with increased overdose risk. Compared with dosages of 1 to less than 20 MME per day, dosages of 50 to less than 100 MME per day were found to increase risks for opioid overdose by factors of 1.9 to 4.6, with absolute risk difference approximation of 0.15% for fatal overdose and 1.40% for any overdose.[114] Dosages of 100 MME or more per day were found to increase risks for opioid overdose by factors of 2.0 to 8.9 relative to dosages of 1 to less than 20 MME per day, with absolute risk difference approximation 0.25% for fatal overdose and 4.04% for any overdose. Veteran Administration's patients with chronic pain who died of overdoses related to opioids were found to have been prescribed higher mean opioid dosages (98 MME/d) than controls (48 MME/d) and that above 200 MME per day, there was a continued increase in mortality rates."[115]

The presentation of a prescription for an excessive quantity of an opioid, or multiple opioids on the same day or within a period of time to cause overlap, was known or should have been known as a red flag requiring investigation by the pharmacist before dispensing the drug. That investigation would need to determine whether a legitimate patient-prescriber relationship existed validating the issuance of the prescription, the safety of the prescribed drug(s) and dose(s) for the patient (particularly any dose exceeding recommended and safe dosages and MME values of greater than 90MME per day), and the possible existence of fraud or diversion.

The excessive dispensing flag is calculated as follows:

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[109] Kim Dunn, Kathleen Saunders, Carolyn Rutter, et al., *Opioid prescriptions for chronic pain and overdose: a cohort study*, Ann Intern Med 2010; 152:85–92.
[110] Amy Bohnert, Marcia Valenstein, Matthew Bair, et al., *Association between opioid prescribing patterns and opioid overdose-related deaths,* JAMA 2011;305:1315–21.
[111] Tara Gomes; Muhammad M. Mamdani; Irfan A. Dhalla; et al., *Opioid dose and drug-related mortality in patients with nonmalignant pain,* Arch Intern Med 2011; 171:686–91.
[112] Leonard J. Paulozzi, Christopher M. Jones, Karin A. Mack, Rose A. Rudd, *Vital signs: overdoses of prescription opioid pain relievers—United States, 1999–2008,* MMWR Morb Mortal Wkly Rep 2011; 60:1487–92.
[113] Susan Okie, *A flood of opioids, a rising tide of deaths,* N Engl J Med 2010; 363:1981–5.
[114] PUBLIX-MDLT8-00149649 at 00149655 (P-PUB-0728) (Leonard Ex. 10) (Publix recognized the increased risk of overdose in patients taking over 50 MME per day).
[115] Deborah Dowell, Tamara M. Haegerich, & Roger Chou, CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016JAMA. 2016 April 19; 315(15): 1624–1645. doi:10.1001/jama.2016.1464.

10. Patient was dispensed an opioid prescription of over 200 MME per day before December 31, 2018 or over 90 MME per day after January 1, 2018.

Chain Pharmacies' policies and the NABP Stakeholders report recognize excessive dispensing as a red flag:

> Kroger: "The patient presents w/ a higher than usual quantity"[116] and/or "The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in your area."[117] "Certain dosing of opioids should raise certain red flags to the dispensing pharmacist -Doses: Morphine Equivalent Dose >200 mg/day, oxycodone >80 mg/day; methadone >40 mg/day, hydromorphone >30 mg/day."[118]
>
> Publix: "The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in your area" or "a new patient presents a prescription for a large quantity of a controlled substance."[119]
>
> Walmart: "prescription is for a large quantity (especially controlled substances)"/ "prescription is for a large number of a particular strength" (POM 1311 2009)[120], "prescription presented is for an unusually large quantity or high starting dose" (POM 1311 2015).[121]
>
> CVS: "Appropriateness of Therapy: Overprescribing large doses of controlled substances to patients." (Note in 2012 they told pharmacists to contact prescriber if "concerns" about type and quantity "e.g., oxycodone 30 mg prescriptions for more than 180 dosage unit").[122]
>
> Walgreens: "Prescriptions presented is for an unusually large quantity or high starting dose."[123] The Good Faith Dispensing program notes: "Increased frequency of prescriptions for same controlled drug: for quantities beyond those normally prescribed."[124] It also asks whether there is a trend, "unusual dosages, directions, or quantities beyond those normally prescribed."[125]
>
> Rite Aid: "Prescription is for an excessive quantity" and "Question high doses of controlled substances with excessive quantities for patients new to Rite Aid."[126]

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[116] Kroger-MDL00009357, at 9383.
[117] *Id*. at 9378.
[118] Kroger-MDL000018716, at 18727.
[119] PUBLIX-MDLT8-00002439 at 00002475.
[120] WMT_MDL_000069077.
[121] WMT_MDL_000042957.
[122] 2012, ROPP-0061 – Protocol for Dispensing Narcotic Drugs for Pain Treatment, CVS-MDLT1-000081566.
[123] WAGMDL00054510 (Note this is not in GFD, this is in training "Pharmacist GFD Review").
[124] WAGMDL00008106.
[125] *Id.*
[126] Rite_Aid_OMDL_0044309.

Interestingly, when applying Kroger's own excessive dispensing criteria (Morphine Equivalent Dose >200 mg/day, oxycodone >80 mg/day; methadone >40 mg/day, hydromorphone >30 mg/day[127]), there is an increase in the number of prescriptions that would have flagged for excessive dispensing compared to those flagged by Red Flag 10.

Pattern Prescribing

Pattern prescribing presents as a red flag when prescriptions are presented by multiple patients for the same medications, same strengths, approximately same quantities, and directions for use.[128] Prescribing the same medications to multiple patients erroneously supposes that the patients suffered from the same disease, exhibited the same symptoms, possessed identical patient factors (height, weight, metabolism rate, and allergies for example), took other medications that were identical, and suffered from the same adverse effects or contraindications. Clinically and in the usual and customary practice of pharmacy, this is not the case and would have served as a red flag regarding the prescribing of the practitioner and validity of the prescriptions. Pattern prescribing flag is as follows:

> 11. An opioid was dispensed to at least 4 different patients on the same day and the opioid prescriptions were for the same base drug, strength and dosage form and were written by the same prescriber.

Chain Pharmacies' policies recognize pattern prescribing as a red flag:

> Kroger: "A number of people appear simultaneously, or within a short time, all bearing similar prescriptions (same drug, strength, quantity) from the same prescriber."[129] "Does this prescriber consistently order the same drugs, strengths, quantity or directions?" And "[a]re prescriptions very similar to others from this prescriber?"[130]
>
> Publix: "A number of patients appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician."[131]

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[127] Kroger-MDL0001871

[128] *Pharmacy Doctors Enterprises, Inc.*, 789 Fed. Appx. at 730 ("prescriptions written by the same doctor on the same day for the same strength of the same drug" is a red flag); *East Main Street Pharmacy*, *supra*, at 66157 ("[a]dditional red flags include '[m]aximum doses being seen for every single patient, lack of individuation of therapy, certain patterns from physicians of potential abuse of seeing the same types of controlled substances over, and over, and over, again.'"); *Holiday CVS*, *supra*, at 62318 ("prescriptions for the same drugs, the same quantities from the same doctor without any kind of variability or change considering the different patients that come into the pharmacy" is a red flag); *Id.* at 62333 (identifying "pattern prescribing" by a physician as an "unresolvable" red flag).

[129] Kroger-MDL00009357 at 00009378.

[130] Kroger-MDL00018716 at 00018729.

[131] PUBLIX-MDLT8-00002439 at 00002475.

Walmart POM 1311 (2015): "Prescriber prescribes the same medication, with the same directions, for the same quantity for a large number of individuals."[132]

CVS: Prescribe the same medication in the same dosage amount to most or all of their patients"[133] and "Routinely prescribes the same combination of pain drugs for most or all of their patients."[134]

Walgreens: "Prescriber prescribes the same medication, with the same directions, for the same quantity for a large number of individuals."[135]

Rite Aid: "The prescriber writes for the same or similar medications in the same dosage quantities to most or all of his/her patients" (e.g., oxycodone 30mg, 180 dosage units)" and "[t]he prescriber routinely prescribes the same "cocktail" or combination of drugs for pain treatment to most or all of his/her patients."[136]

Early fills/refills:

As trained pharmacists and licensed pharmacies were aware, when an individual requests that a controlled-substance prescription be filled significantly early, it raises a red flag regarding abuse or other diversion because it suggests that the individual is either taking a higher quantity than prescribed or diverting at least some of the medications to other individuals. The early refill flag is calculated as follows:

12. An opioid prescription was refilled more than 5 days before the patient's previous prescription should have run out.

In calculating this flag, I used a strict definition of a refill to mean a prescription was written on the same day for the same drug, same dose, day's supply by the same prescriber. However, any prescription for an opioid which is filled five days before a prior prescription for the same drug, dose, and day's supply written by the same doctor poses a risk to the patient and is indicative of diversion or abuse.

Chain Pharmacies' policies and the Stakeholders report recognize early fills/refills as a red flag:

Kroger: "Patient is repeatedly requesting early refills of CS or opioids, benzos or Carisoprodol"[137] The patient appears to be returning too frequently. A prescription which

[132] WMT_MDL_000042957.
[133] 2012, ROPP-0061 – Protocol for Dispensing Narcotic Drugs for Pain Treatment, CVS-DR22-000001062.
[134] *Id.*
[135] WAGCASF00077753 at 00077760.
[136] Rite_Aid_OMDL_0044309 at 0044311.
[137] KrogerMDL00009357 at 9383.

should have lasted for a month in legitimate use is being refilled on a biweekly, weekly or even a daily basis."[138]

Publix: "The patient requests early refills or states that the previous fill was lost or stolen."[139]

Walmart: Walmart had a policy, POM 1318 (2011),[140] that directly addressed filling controlled substances early. Walmart's pharmacy management software, Connexus, alerted pharmacists when requests were made to fill prescriptions more than 72 hours ahead of the next permitted fill date of a controlled-substance prescription. In 2015, Walmart added "individual routinely attempts to obtain an early refill on controlled substances." POM 1311 (2015).[141] In 2019 Walmart added "An *unjustified* early refill request" as a red flag in POM 1311 (emphasis added).[142]

CVS: "Early fill – Customer attempting refill early or consistently showing up at the first available moment when refill can be obtained under standard practices." (2014).[143]

Walgreens: "Consistent requests for early refills" or "Individual routinely attempts to obtain an early refill on controlled substances"[144] (As of 2013, used 8 days early for a 30-day supply, 90-days supply should be X days/percent (WAGMDL00437788)).

Rite Aid: "Early refills on controlled substances, where they paid cash stating lost prescription, going away on vacation, etc."[145] Rite Aid explains that "[e]arly refills for controlled substances should not occur more than 48 hours in advance (if allowed by State law) of the scheduled exhaustion of their current prescription supply based on the directions provided by the prescriber."[146]

NABP Stakeholders: "Pattern" of "frequently running out of medication for controlled substances early" and "controlled substance refill patterns being inconsistent with regular refill patterns for non-controlled chronic prescription medications."[147]

Opioids Days' Supply:

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[138] KrogerMDL00009357 at 9377.
[139] PUBLIX-MDLT8-00002439 at 00002475.
[140] WMT_IN_AG_00000153.
[141] WMT_MDL_000042957.
[142] WMT_MDL_000067636.
[143] *See* March 2011, Course #800131, Biannual Compliance Training, CVS-NYAG-000030693.
[144] 6/2011 Controlled Substance Prescriptions and GFD, WAGMDL00054509.
[145] Rite_Aid_OMDL_0044309 at 0044312.
[146] *Id*.
[147] NABP_00022121 at 00022136.

Opioids are inherently dangerous drugs that require strict adherence to the recommended doses and duration in order to avoid patient harm and reduce the risk of addiction, abuse, and diversion. Prescription opioids and heroin are chemically similar and can produce a similar euphoric feeling or high. As a result, opioids present a great risk of diversion. Prescription opioids used for pain relief should be prescribed and taken for a short time given their addictive properties and binding to and activation of opioid receptors on cells located in many areas of the brain, spinal cord, and other organs in the body, especially those involved in feelings of pain and pleasure.[148] When opioids attach to these receptors, they block pain signals sent from the brain to the body and release large amounts of dopamine throughout the body. This release can strongly reinforce the act of taking the drug, making the user want to repeat the experience. A patient prescribed opioids for longer than six months increases the risk of abuse, addiction, and diversion and is a red flag. A pharmacist before dispensing the medication would need to determine whether a legitimate patient-prescriber relationship existed validating the issuance of the prescription, the safety of the prescribed drug and dose(s) for the patient given the length of treatment, and overlapping supply of medications and potential fraud and diversion. The opioid day's supply flag is:

13. A patient was dispensed more than 210 "days of supply" of all opioids combined in a 6-month period:

Payment for an opioid by cash:[149,150,151]

Paying cash for a prescription is a red flag of diversion. Oftentimes people who are paying cash for opioids are engaged in diversion and seek to obfuscate the purchase of controlled substances from review by payors and insurance companies. The likelihood of diversion increases in circumstances in which the patient pays for an opioid prescription with cash when they otherwise have insurance. The various programs that cover the cost of prescription medications afford little need to pay cash for prescriptions that would likely be covered by insurance thus avoiding out-of-pocket expenses for the individual.[152, 153] The paid in cash flag is simply:

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[148] National Institute of Drug Abuse. Prescription Opioid Drug Facts, May 2020.
[149] Federal Register / Vol. 83, No. 49 / Tuesday, March 13, 2018 / Notices.
[150] Federal Register / Vol. 81, No. 218 / Thursday, November 10, 2016 / Notices.
[151] Federal Register / Vol. 75, No. 207 / Wednesday, October 27, 2010 / Notices.
[152] Federal Register / Vol. 81, No. 218 / Thursday, November 10, 2016 / Notices.
[153] *Jones Total Health Care Pharmacy, LLC*, 881 F.3d at 828 ("cash purchases" of prescriptions is a red flag); *Pharmacy Doctors Enterprises, Inc.*, 789 Fed. Appx. at 730 (cash payments for prescriptions is a red flag); *Holiday CVS, supra*, at 62318, fn. 9 (cash payments for prescriptions is a red flag); 62326 ("large quantities of people paying cash" is a red flag), 62331 ("patients between the ages of 25 and 40 with cash" is a red flag), 62332 ("According to [Dr.] Doering [DEA expert], 'typically, people who may be diverting or otherwise misusing their drugs will pay cash.'"); *East Main Street Pharmacy, supra*, at 66150 (high percentage of cash payments compared to national average is a red flag); *id.* at 66158 (according to Dr. Sullivan, the DEA's testifying expert, this "is an obvious example of a pharmacy profiting from drugs that are most likely being abused or diverted for sale on the street' and that '[a]ny reasonable pharmacist knows that a patient that wants to pay cash for a large quantity of controlled substances is immediately suspect'").

14. A patient was dispensed an opioid and paid cash:

Chain Pharmacies' policies and the Stakeholders report recognizes cash payments as a red flag:

> Kroger: "Patient pays cash for prescriptions."[154]
>
> Publix: "The patient only pays cash for controlled substance prescriptions."[155]
>
> Walmart POM 1311 (2015): "Individual insists on paying cash or insists on paying cash for controlled substances even though insurance is on file."[156]
>
> CVS: "Cash – Cash payment for prescriptions, particularly if RxConnect indicates the patient has insurance." In 2011, 6.2.11 Identifying Forged or Altered Prescriptions. "Patient asks to pay cash for prescription."[157]
>
> Walgreens: "Individual pays cash, or insists paying cash for controlled substances even though insurance is on file." "Does the patient request to pay by cash or by using a cash discount card (in a possible attempt to circumvent third party billing restrictions)"[158]
>
> Rite Aid: "Payment trends (e.g., always pays cash for controlled substances, but has insurance)." Later, Rite Aid added flags for prescriptions "paid for by Cash and/or Discount Cards.[159]
>
> NABP Stakeholders Document: "Requesting to pay cash for a controlled substance prescription, when it has been documented that he/she has insurance that would normally cover the prescription (cash)."
>
> NACDS: "Patient pays with cash," citing *Holiday and East Main*, in which nearly 87% of a physician's patients "paid case for their prescriptions," a "red flag as '[a]ny reasonable pharmacist knows that a patient that wants to pay cash for a large quantity of controlled substances is immediately suspect.' *East Main*, 75 FR at 66164."[160]

1. Summary of Red Flags

The number of red flags identified in Defendant's dispensing data is indicative of a pattern of diversion in Georgia. Roughly 194,566, or 46.9%, of all opioid prescriptions dispensed by Kroger

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[154] KrogerSmithNMAG000348.
[155] PUBLIX-MDLT8-00002439 at 00002475.
[156] WMT_MDL_000042957.
[157] ROPP-00059, CVS-MDLT1-000081559.
[158] GFD, WAGMDL00742666 at 742668.
[159] Rite_Aid_OMDL_0044327.
[160] WMT_MDL_000891159.

pharmacies in Cobb County contained red flags.[161] Approximately 305,069, or 45.5%, of all opioid prescriptions dispensed by Publix pharmacies in Cobb County contained red flags.[162] Every red flag must be resolved before each prescription for a controlled substance is dispensed. Opioids are extremely addictive and highly subject to abuse as a result, all red flags are concerning. One would expect given the dangerous nature of these drugs and the presentation of well-known red flags that only a small percentage of prescriptions would be dispensed with unresolved or unresolvable red flags.

Red flags need not always be specific to the prescription being presented. A pharmacy should also be reviewing its dispensing data to take into consideration the totality of the circumstances, including the practitioner's prescribing patterns across different patients, e.g., large quantities, high-risk combinations, and similar diagnosis codes. That "totality of responsibility" requires the pharmacy or DEA registrant corporation to monitor the overall controlled substance volume and pertinent dispensing data. *See e.g.*, *U.S. v. Lawson*, 682 F.2d at 483 ("Lawson willingly ignored every signal that he should question the volume of controlled drugs being dispensed from his pharmacies."). When a prescription for a controlled substance contains a red flag that is not resolved, each subsequent controlled substance prescription for that patient or prescriber is subject to flagging until all prior flags have been investigated and resolved.

In situations where diversion is suspected, the pharmacist and the pharmacy have a responsibility to report this suspicion to the appropriate regulatory and law enforcement authorities and document the facts of the situation and actions taken and refuse to fill the prescription.

Chain Pharmacies have also identified and memorialized the following additional red flags of diversion:

- Physician writes large number or percentage of prescriptions for controlled substances.
- Physician prescribes controlled substances outside of his ordinary practice.
- Recurring pattern of prescribing the same controlled substances to multiple patients which suggests the physician is operating a pill mill.
- Physician engages in the unauthorized practice of medicine.
- Physician no longer holds a DEA license.
- Pharmacy and/or pharmacist has excessive volume and rate of growth of dispensing controlled substances.
- Pharmacy and/or pharmacist dispensing data shows early fills "weeks early" on several occasions.

2. Additional Red Flags of Diversion

[161] Expert Report of Craig McCann, January 24, 2024, page 110.
[162] Expert Report of Craig McCann, January 24, 2024, page 111.

There are red flags of diversion that a dispensing operating system could not detect. Thus, it is critical that all pharmacy personnel be trained to identify and address these indicators of potential diversion. One category of these flags is suspicious behavior of the patient. Pharmacies should have appropriate training materials and controls to assist pharmacists and technicians in the identification of such behaviors. When the customer drops off a prescription at the pharmacy, observations of the patients' behavior should be made as part of the required validation of the prescription. Indicators of possible signs of diversion, or suspicious behavior include stumbling while walking, slurred speech, appearance of intoxication, or customers "appearing like they may not need the medication" or "appearing like they may be high." *Holiday CVS, L.L.C., d/b/a CVS/ Pharmacy Nos. 219 and 5195*; Decision and Order, 77 Fed. Reg., No. 198 (2012), at 62326. Suspicious behavior that may indicate signs of diversion also include customers arriving in groups to get narcotic prescriptions filled. Multiple out-of-area patients from the same town or area is also a sign of diversion. *Id*. at 62319, 62331. Customers requesting their prescriptions by the brand name, by descriptions, or by street slang can also be a sign of diversion. For example, the terms "the M's", "the Blues," or "Mallinckrodt Blues" are common terms which are red flags and may be a sign of diversion. *Id.* at 62321, 62344. When such behavior is observed it must be documented in the patient profile.

In addition to the foregoing red flags, Defendants have also identified and memorialized the following in its policies:

- Pharmacists have a corresponding responsibility to dispense legitimate controlled substance prescriptions.[163]
- Pharmacists must use of state PDMP.[164]
- Pharmacists must follow documentation requirements.[165]
- Pharmacists must follow DEA guidance.[166]

3. Multiple Red Flags

As each red flag is a potential indication of diversion, it is axiomatic that when a prescription is presented with multiple red flags the likelihood of diversion increases greatly. There are countless combinations of red flags that could exist with a single prescription. In each instance, every red flag must be resolved before the prescription is filled. Many DEA cases describe various

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[163] KrogerSmithNMAG000348; PUBLIX-MDLT8-00149649 at 00149651.
[164] KrogerSmithNMAG000348. Despite acknowledging the importance of PDMP usage as a means to prevent the diversion of controlled substances, Publix does not require its pharmacies to check the state PDMP prior to dispensing opioids unless the state where they practice mandates it. Nov. 15, 2022, Jillanne Smith Deposition (hereafter "Smith Dep."), 369. In fact, Publix was and is aware that it is "not the norm" for its Georgia pharmacists to check the GA PDMP when filling a controlled substance prescription. PUBLIX-MDLT8-00074321
[165] KrogerMDL00002122 at 00002150; KrogerMDL00009357 at 00009385; PUBLIX-MDLT8-00149649 at 00149658.
[166] KrogerMDL00009357 at 00009385. (Kroger providing current trends and reminders); PUBLIX-MDLT8-00058608 at 00058609.

combinations of red flags. For example, the confluence of out of state patients on a single day receiving the same medications, in the same quantities, from the same prescriber, would be considered a combination of red flags that would each need to be resolved before filling a prescription. Holiday CVS, L.L.C., d/b/a CVS/ Pharmacy Nos. 219 and 5195; Decision and Order, 77 Fed. Reg., No. 198 (2012), at 62333. Similarly, the combination of flags of cash-discount method of payments, out of state or out of area patients, and the distance between the patients' home addresses and the prescriber would also demonstrate a combination of red flags that must all be resolved. *Id*. at 92333.

Chain Pharmacies should have had systems and programs in place to detect, report and store red flag information in a format that could be easily retrieved and reviewed by corporate headquarters, its pharmacists, and regulators. If the information were stored in this format, it could have been used to identify patients and potentially their prescribers engaged in diversion.

Kroger's dispensing data revealed multiple red flags. There were 194,566 opioid prescriptions dispensed in Cobb County which triggered at least one red flag. From that number of red flagged prescriptions, 101,558 opioid prescriptions triggered two or more red flags and 43,655 of the opioid prescriptions triggered 3 or more flags.[167]

Summary of Opioid Prescriptions - Flagged Multiple Times
Cobb County, GA
Nonrecurrent

Defendant	Kroger	
Total # of Opioid Prescriptions	**414,636**	
Opioid Prescriptions Flagged - 2+ Methods	101,558	24.49%
Opioid Prescriptions Flagged - 3+ Methods	43,655	10.53%
Opioid Prescriptions Flagged - 4+ Methods	18,816	4.54%
Opioid Prescriptions Flagged - 5+ Methods	6,718	1.62%
Opioid Prescriptions Flagged - 6+ Methods	2,414	0.58%
Opioid Prescriptions Flagged - 7+ Methods	678	0.16%
Opioid Prescriptions Flagged - 8+ Methods	142	0.03%
Opioid Prescriptions Flagged - 9+ Methods	25	0.01%
Opioid Prescriptions Flagged - 10+ Methods	2	0.00%
Opioid Prescriptions Flagged - 11+ Methods	0	0.00%

Notes

[1] Defendant	Date Range
Kroger	12/2008 - 6/2018

Publix's dispensing data also revealed multiple red flags. There were 305,069 opioid prescriptions dispensed in Cobb County which triggered at least one red flag. From that number of red flagged

[167] Expert Report of Craig McCann, January 24, 2024, page 110 and Appendix 7 at page 1611.

prescriptions, 131,055 opioid prescriptions triggered 2 or more red flags and 53,306 of the opioid prescriptions triggered 3 or more flags.[168]

Summary of Opioid Prescriptions - Flagged Multiple Times
Cobb County, GA
Nonrecurrent

Defendant	Publix	
Total # of Opioid Prescriptions	**669,828**	
Opioid Prescriptions Flagged - 2+ Methods	131,055	19.57%
Opioid Prescriptions Flagged - 3+ Methods	53,306	7.96%
Opioid Prescriptions Flagged - 4+ Methods	21,255	3.17%
Opioid Prescriptions Flagged - 5+ Methods	7,936	1.18%
Opioid Prescriptions Flagged - 6+ Methods	2,802	0.42%
Opioid Prescriptions Flagged - 7+ Methods	761	0.11%
Opioid Prescriptions Flagged - 8+ Methods	166	0.02%
Opioid Prescriptions Flagged - 9+ Methods	41	0.01%
Opioid Prescriptions Flagged - 10+ Methods	10	0.00%
Opioid Prescriptions Flagged - 11+ Methods	0	0.00%

Notes

[1] Defendant	Date Range
Publix	5/2006 - 5/2019

F. Notice to Chain Pharmacy Defendants from DEA Investigations and Suspensions

From their own past experience, and publicity surrounding other enforcement actions, the large chain pharmacy companies knew that if they, and their pharmacists, failed to comply with their legal obligations when dispensing controlled substances, they could face an enforcement action. Through these actions, Defendants were given specific and detailed warnings from the DEA of the red flags and risks of diversion.[169]

In 2005, the DEA investigated Kroger's pharmacies for systemic violations of the Controlled Substances Act by the company's pharmacies in the Denver area. Kroger entered a settlement

[168] Expert Report of Craig McCann, January 24, 2024, page 111 and Appendix 8 at page 2051.
[169] *See e.g.*, KrogerMDL00009357, at 9364 (Kroger's training materials on DEA Trends reference DEA investigations and enforcement actions against CVS and Walgreens); Kroger MDL00002421 at 00002423 (listing recent fines and actions against CVS and Walgreens); PUBLIX-MDLT8-00119094 at 95 (P-PUB-0309-A) (Publix listing DEA settlements in compliance update); PUBLIX-MDLT8-00066086 at 00066087 (Publix highlighting CVS action and additional red flag signs of diversion); WMT_MDL_00675777;

agreement with the DEA pursuant to which it agreed to pay $7,000,000[170] and to "implement a Comprehensive Regulatory Compliance Program,"[171] and to train all of its employees pursuant to the Compliance Program in all of its 1,900 pharmacies nationwide.[172]

The DEA issued Orders to Show Cause against both Walgreens and Walmart in 2009. Both were initiated in relation to specific stores but resulted in Walgreens and Walmart each entering into separate Memoranda of Agreement ("MOAs") in 2011 that required nationwide reforms to their pharmacy policies, procedures, and programs.[173] Walgreens agreed in its April 2011 MOA to "maintain[ing] a compliance program to detect and prevent diversion of controlled substances" as required under federal law." In that MOA, Walgreens expressly agreed that the program would include training and "procedures to identify the common signs associated with the diversion of controlled substances."

Walmart similarly agreed in 2011 to adopt a national compliance program intended to ensure that it fulfilled its legal obligations when filling controlled-substance prescriptions. In the MOA, Walmart committed to, among other things, "maintain a compliance program, updated as necessary, designed to detect and prevent diversion of controlled substances as required by the Controlled Substances Act"; create a process that would ensure that its pharmacists were identifying common signs of diversion. Specifically, the MOA required that Walmart's compliance program would include procedures to ensure that pharmacists identified red flags to include procedures to identify the common signs associated with the diversion of controlled substances, including but not limited to, doctor-shopping, requests for early refills, altered or forged prescriptions, prescriptions written by doctors not licensed to practice medicine in the jurisdiction where the patient is located, and prescriptions written for other than a legitimate medical purpose by an individual acting outside the usual course of his professional practice. It also agreed that if one of its pharmacists did conclude that a prescription was not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice, was forged, or had been altered, and refused to fill that prescription, Walmart would notify the local DEA field office within seven business days of the refusal to fill. Walmart also specifically agreed to collect reports from its pharmacists when those pharmacists determined that controlled substance prescriptions were invalid and refused to fill them. The MOA was in effect from March 2011 through March 2015.

Both Walmart and Walgreens would face further enforcement action. This included a 2012 Order to Show Cause against Walgreens involving its Florida pharmacies, which again uncovered conduct implicating more widespread failures at a corporate level, not limited to stores in Florida.

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[170] Kroger-MDL00031079 at ¶ 5.
[171] *Id*. at ¶ 7.
[172] *Id*. at Exhibit A. *See also* Press Release, Drug Enforcement Administration, Record 7 Million Dollar Settlement, Kroger Corporation establishes corporate wide compliance program (Oct. 24, 2005), https://www.dea.gov/press-releases/2005/10/24/record-7-million-dollar-settlement; US-DEA-00012570 at _00017-00021 and Kroger PowerPoint Presentation attachment (P-32287).
[173] WMT_MDL_000043490, WAGMDL00757802

The 2012 Show Cause Order specifically addressed the 2-Drug Combination red flag discussed above, noting that Walgreens pharmacy filled prescriptions for individuals presenting prescriptions for combinations of controlled substances known to be highly abused, such as oxycodone and benzodiazepines.[174] In 2015, Walmart settled claims that its pharmacists at a store in Rhode Island filled obviously forged controlled substance prescriptions.[175] In December of 2020, the U.S. Department of Justice ("DOJ") filed a lawsuit against Walmart alleging nationwide dispensing failures.

CVS has faced repeated enforcement actions, ranging from an action concerning conduct dating back to 2006 to the present. Before taking action against CVS in 2012, DEA hosted a December 8, 2010, meeting attended by CVS' Head of Pharmacy Professional Services, Papatya Tankut and the CVS district supervisor.[176] At that time, CVS's counsel acknowledged "that CVS was aware of the pill mill and/or pain clinic situation and the diversion of controlled substances, primarily oxycodone, in Florida."[177] CVS also acknowledge receipt of an October 2010 plea from a local sheriff "to work with law enforcement and closely scrutinize the prescriptions they receive."[178]

CVS was advised by the DEA:

> that the diversion of oxycodone, primarily originating from purported pain clinics, involves fraudulent prescriptions, doctor shoppers, and unethical doctors. CVS was further advised of the typical "red flags" associated with the diversion of controlled substances that a pharmacy should be familiar with in order to carry out its corresponding responsibility to ensure that the controlled substances are dispensed for a legitimate medical purpose. Some of the "red flags" discussed included: (a) many customers receiving the same combination of prescriptions *(i.e.,* oxycodone and alprazolam); (b) many customers receiving the same strength of controlled substances *(i.e.,* 30 milligrams of oxycodone with 15 milligrams of oxycodone and 2 milligrams of alprazolam); (c) many customers paying cash for their prescriptions; (d) many customers with the same diagnosis codes written on their prescriptions (i.*e.,* back pain, lower lumbar, neck pain, or knee pain); and (e) individuals driving long distances to visit physicians and/or to fill prescriptions.[179]

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[174] 2012 Orders to Show Cause issued to Walgreens (WAGMDL00387708).
[175] WMT_MDL_000043497.
[176] Declaration submitted by then Deputy Assistant Administrator for DEA's Office of Diversion Control Joseph Rannazzisi, in *Holiday CVS, L.L.C., v. Holder*, Civ. No. 1:12-cv-191 (D. D.C Feb. 24, 2012).
[177] *Id.* at ¶ 27.
[178] *Id*. at ¶ 29.
[179] *Id.* at ¶ 28.

During the December 2010 meeting, CVS also acknowledged awareness of an increase in oxycodone prescriptions at Florida CVS stores.[180] DEA discussed "a summary from DEA's Automation of Reports and Consolidated Orders System (ARCOS) records" showing that the increase at one store, which was already ordering "more than four times the amount of oxycodone a typical pharmacy orders in one year" in 2006, was "huge," with a more recent 10-month history showing the store ordered "more than thirty times what a typical pharmacy ordered in one year."[181] During the same meeting, DEA also made clear that CVS's instruction to its pharmacists to call the prescriber "representatives that verifying that the prescription was written by a physician was not the same as making an independent determination that the prescription was written for a legitimate medical purpose in the usual course of professional practice."[182]

"On August 12, 2011, DEA hosted a second meeting with CVS at the DEA Weston Resident Office," attended by "24 supervisors/managers from various South Florida CVS pharmacies."[183] "The presentation included," among other information, "statistical information" that "showed drastic increases in prescription drug overdose deaths."[184] At that meeting, the DEA again reminded CVS of corresponding responsibility under the CSA and:

> the typical "red flags" associated with the diversion of controlled substances that a pharmacy should be familiar with in order to carry out its corresponding responsibility to ensure that the controlled substances are dispensed for a legitimate medical purpose. Some of the "red flags" discussed included: (a) many customers receiving the same combination of prescriptions; (b) many customers receiving the same strength of controlled substances; (c) many customers paying cash for their prescriptions; (d) many customers with the same diagnosis codes written on their prescriptions; (e) individuals driving long distances to visit physicians and/or to fill prescriptions; (f) customers coming into the pharmacy in groups, each with the same prescriptions issued by the same physician; and (g) customers with prescriptions for controlled substances written by physicians not associated with pain management (i.e., pediatricians, gynecologists, ophthalmologists, etc.).[185]

After the DEA executed Administrative Inspection Warrants at two Florida CVS stores discussed in the meetings, interviews with CVS pharmacists revealed that no one spoke with the pharmacist in charge of one store about the staggering amounts of oxycodone discussed in CVS's December 2010 meeting with the DEA and the pharmacist was unfamiliar with multiple red flags.[186] Other employees believed it was not their job to "police the patients" and described measures the stores

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[180] *Id.* at ¶ 29.
[181] *Id.* at ¶ 31.
[182] *Id.* at ¶ 30.
[183] *Id.* at ¶ 33.
[184] *Id.* at ¶ 34.
[185] *Id.* at ¶ ¶ 35-36.
[186] *Id.* at ¶ 41.a.

had implemented as they filled prescriptions that were "probably were not legitimate."[187] These included daily limits designed to "ensure that the pharmacy had enough oxycodone 30mg to fill the prescriptions for 'real pain patients'" and the job duty of one employee who acted as the "bouncer" for a CVS store.[188] The CVS employees "consistently ignored the red flags of controlled substance diversion," and until CVS faced heightened DEA scrutiny, filled prescriptions for more than twenty prescribers who later faced enforcement action themselves—none of whom were located in the same city as the stores and most of whom were some distance away.[189]

The record of these actions highlights not only admonitions about the pharmacies' obligations, but the importance of these requirements. As Deputy Assistant Administrator Rannazzisi, in *Holiday CVS, L.L.C., v. Holder*, Civ. No. 1:12-cv-191 (D. D.C Feb. 24, 2012), explained: "When registrants at every level—practitioners, pharmacies and distributors—fail to fulfill their obligations," the CSA's "necessary checks and balances collapse."[190] And "[b]ecause pharmacies are the entity providing the controlled substances to the end user, they are often the last major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market."[191] Florida's State Health Officer and Surgeon General in July 2010 issued a "statewide public health emergency declaration in response to the ongoing problem of prescription drug abuse and diversion in Florida"—a problem whose impact was felt well outside the state, as oxycodone and other controlled substances such as alprazolam from Florida was being "illegally redistributed in states along the entire east coast and Midwest."[192]

Following the DEA actions and injunctive orders, other chain pharmacies implemented companywide policies to combat diversion of controlled substances. The 2011 MOU between Walgreens and the DEA memorialized basic pharmacy standards to be implemented and enforced. These obligations include the continued maintenance of a compliance program and routine training to reorient employees of their responsibilities under the CSA and DEA regulations.[193] This program was put in place to "detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations."[194] In spite of these prior DEA enforcement actions and the anti-diversion efforts that these pharmacies undertook in response to the enforcement actions, ineffective due diligence remained, contributing to large numbers of red flag prescriptions dispensed by these companies into the communities they served without adequately reviewing and resolving those red flag prescriptions.

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[187] *Id.* at ¶ 41.
[188] *Id.*
[189] *Id.* at ¶¶ 43 & 54-55.
[190] *Id.* at ¶ 10.
[191] *Id.* (explaining that "[i]t is, therefore, incumbent on pharmacies to ensure that controlled substances are only dispensed pursuant to valid prescriptions issued for legitimate medical purposes in the usual course of professional practice").
[192] *Id.* at ¶¶ 15, 20.
[193] DEA, Administrative Memorandum of Agreement, at 2, https://www.dea.gov/sites/default/files/divisions/mia/2013/mia061113_appendixa.pdf.
[194] DEA, Administrative Memorandum of Agreement, at 2, https://www.dea.gov/sites/default/files/divisions/mia/2013/mia061113_appendixa.pdf.

As a result, the Florida Attorney General brought civil actions against CVS and Walgreens, and Trumbull and Lake counties filed separate public nuisance lawsuits against Walmart, CVS, and Walgreens as part of the federal opioid MDL. Subsequently, CVS and Walgreens entered settlement agreements with the Florida Attorney General that contained several proactive diversion prevention policies [195] In the MDL, the Court entered a judgment and injunctive order against Walmart, CVS, and Walgreens, directing each defendant to implement diversion policies and programs similar to those set forth in the Florida settlements. [196] Both the Florida settlements and the MDL's injunctive order sought to remedy the oversupply of prescription opioids through enhanced due diligence measures and recordkeeping that include, among others, requirements for

- The creation of a Controlled Substance Compliance Committee;
- Mandatory training of employees;
- Identification, resolution, and documentation of red flags for dispensed prescriptions and for those that pharmacists refused to fill--"The documentation should provide sufficient details in order that any subsequent reviewer will have a clear understanding of how each Flag was resolved for any review or inquiry for auditing or regulatory purposes. The documentation must be available and easily accessible to all pharmacists employed by the Defendant at all of its retail pharmacies."[197];
- A process to check the licensure status of prescribers of controlled substances;
- A process to review prescribing patterns and practices utilizing algorithms to analyze the pharmacies dispensing data and other data and information to investigate prescribers; and
- Proactive due diligence and site visits of their pharmacy stores.

Defendants were well aware of DEA enforcement actions and should have taken steps in the face of such knowledge to enhance their controlled substance policies and procedures. Many chain pharmacies had some versions of these programs in place, albeit not as robust and as effective as needed. Kroger and Publix should have implemented these basic diversion programs and practices years ago. If they had done so, they would have prevented significant diversion of controlled substances in the communities they served.

Kroger

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[195] CVS Settlement Agreement and Release (Mar. 29, 2022), https://www.myfloridalegal.com/files/pdf/page/1DE4F463296C85C18525874F004AF94D/CVSSettlementAgreementwithExhibits.pdf

[196] CVS, Walgreens, Walmart Injunction Order, (Feb. 10, 2023), https://storage.courtlistener.com/recap/gov.uscourts.ohnd.238494/gov.uscourts.ohnd.238494.4893.0.pdf

[197] *Id.*at VIII. F. p. 8

In 2012, Kroger's Pharmacy Compliance Committee ("PCC") began discussions regarding the implementation of a pilot pharmacy employee training program to address compliance.[198] This effort was made years after it should have begun. Further, despite this effort, training remained the "weakest area of compliance for the company" for several years and the initiative remained on hold until at least 2016.[199] This delay left many pharmacists inadequately prepared to safely dispense controlled substances. Moreover, deficiencies with Kroger's pharmacy associate training continued thereafter for years, as evidenced by the results from Kroger's 2018 and 2021 pharmacy surveys. "[I]n some cases pharmacists do not understand due diligence efforts that need to be undertaken and continue to fill prescriptions."[200]

One of Kroger's "highest risk" within DEA compliance is the "pharmacists' inconsistent and often absent understanding of the DEA's expectations for executing proper corresponding responsibility related to the dispensing of controlled substances."[201] It was also brought to Kroger's attention that pharmacists did not "remember receiving any information from Kroger's corporate offices regarding prescription 'red flags.'"[202] Additionally, "pharmacists appeared to know in general about their practice responsibilities but were not fully familiar with the term and meaning of 'corresponding responsibility.'"[203] Kroger failed to adequately train its pharmacists.

Publix

Internal documents show that Publix was cognizant of DEA enforcement actions and fines, including the CVS Holiday case.[204] In response to these events, Publix anticipated the increase of DEA inspections, OCR audits, and litigation and the likelihood that Publix "will be in the hot seat."[205] Additionally, it was not until the CVS actions in 2012 that Publix finally created a written controlled substance dispensing policy that included red flags.[206] However, testimony from a Publix pharmacist in Cobb County shows that Publix did not adequately distribute and make their pharmacists aware of the controlled substance and red flag policy at that time. Shannon Brice, a pharmacist at Publix for over 25 years, testified that she had never seen the 2012 policy until the time of her deposition.[207]

Publix should have updated its pharmacy procedures after it received notice of other chain pharmacies' settlements and injunctive relief requirements. Publix could have consulted publicly available and periodically updated as diversion trends and regulations change. The role of

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[198] *See* February 2012 PCC Minutes at bates KrogerSmithNMAG00013072 at 00013073.
[199] *See* June 2015 PCC Minutes at bates KrogerSmithNMAG00010239_0005.
[200] *Id*. at 0003.
[201] Kroger-MDL00034861 at 00034865.
[202] KrogerSmithNMAG00013077 at 00013079.
[203] *Id*.
[204] PUBLIX-MDLT8-00073501 at 00073502 (P-PUB-0186); PUBLIX-MDLT8-00119094 at slide 2 (P-PUB-0309); PUBLIX-MDLT9-00066086 at 00066087 (P-PUB-0248); PUBLIX-MDLT8-00071835 at 00071852 (P-PUB-0322).
[205] PUBLIX-MDLT8-00119094 at slide 3 (P-PUB-0309).
[206] PUBLIX-MDLT8-00027405
[207] Brice Dep. at 44:5-45:8. See also PUBLIX-MDLT8-00071345

pharmacists in dispensing controlled substances "is critical to the health of patients and helps protect society against drug misuse and diversion."[208] Publix also noted that it "play[s] a major role in the public's health" and that it is imperative that good judgment is used especially when dispensing controlled substances.[209] Registrants must stay abreast of the changes in industry standards as the signs of diversion evolve.[210]

Publix

In 2012, Publix established a guide referencing the identification of red flags in Ch. 8 of the Pharmacy Reference Procedure Guide titled "Regulations and Associated Publix Policies."[211] However, interns, pharmacists, and managers received no formal training on this guidance, including no training on red flags.[212] Corporate reference guides for controlled substances were incomplete and did not contain laws related to these highly diverted drugs.[213] Publix reasoned that "pharmacy associates should know the requirements for a controlled substance prescription."[214] Controlled substance training on red flags and patient care was a "high effort" and "low priority" for Publix.[215] However, the lack of corporate guidance on controlled substances was one of the most common complaints Publix received from pharmacists.[216] Publix did not develop a controlled substance compliance department or hire diversion analysts until 2018.[217] In November of 2018, Publix approved a controlled substance training course for the first time.[218] Though, the controlled substance training was still deemed a "low priority."[219]

Publix could have consulted publicly available material, Publix also noted that it "play[s] a major role in the public's health" and that it is imperative that good judgment is used especially when dispensing controlled substances.[220] Registrants must stay abreast of the changes in industry standards as the signs of diversion evolve.[221]

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[211] PUBLIX-MDLT8-00002439 at 00002475.
[212] King Dep. at 133:2-22-135:17.
[213] PUBLIX-MDLT8-000071345 (P-PUB-0586).
[214] *Id*.
[215] PUBLIX-MDLT8-00119095 (P-PUB-0349).
[216] PUBLIX-MDLT8-00115817 at 00115820 (P-PUB-0719) (Leonard Exhibit 5).
[217] Nov. 4, 2022, Chris Hewell Deposition (hereafter "Hewell III Dep."), 149:24-150:2.
[218] PUBLIX-MDLT8-00072578 (P-PUB-0319); PUBLIX-MDLT8-00079714; Smith Dep., 403:18-25 (Ms. Smith confirming that controlled substance training initiatives were put in place for the first time in 2018).
[219] PUBLIX-MDLT8-00119095; PUBLIX-MDLT8-00079714; PUBLIX-MDLT8-00088571; PUBLIX-MDLT8-00134424; PUBLIX-MDLT8-00134424
[220] PUBLIX-MDLT8-00118914
[221] Respondent suggests that its owner and pharmacists were entitled to a similar briefing, and should be excused from liability because they did not receive such a briefing, it is mistaken. DEA does not have the resources to

Mechanisms such as prescriber blocks are useful tools to prevent diversion. Even today, Publix fails to implement this effective control.[222] There are no "extremes of not filling globally for a Dr." even though this function is easily available on Publix's EnterpriseRx system.[223] The EnterpriseRx system at Publix will not notify pharmacists if a prescriber is banned from writing a controlled substance prescription or generate an automatic block.[224] If an illegal prescription is identified, the pharmacist is supposed to notify corporate by filing out a loss prevention incident report.[225] Publix does not, however, initiate a block of further prescriptions from the provider.[226] Publix has no centralized system to notify or inform its pharmacists about suspicious prescribers nor does it have a standard process for when they are alerted to problematic prescribers by either their own pharmacists or law enforcement. Rather, notification to other pharmacists are limited to notes on the prescription or long chain emails.[227] Yet, this documentation is not an enforced pharmacy policy.[228] Likewise, Publix does not have a store monitoring program to monitor the controlled substance trends of their own stores. They also do not have a centralized tracking for refusals to fill, and they do not allow for blanket refusals to fill for suspicious patients or prescribers known to be or suspected of diverting drugs.[229]

When Publix became aware of modified policies at other chain pharmacies over the years, Publix did not take the opportunity to evaluate its own policies and procedures. In 2019, Publix became aware of a CVS corporate policy refusing to fill drug cocktails that contained opioids, benzodiazepines, and muscle relaxers.[230] Instead of reviewing its own policy regarding drug cocktails, Publix was concerned with keeping up with demand from the influx of patients they would receive as a result of CVS refusals to fill.[231] The lack of initiative to execute controls to prevent diversion demonstrates the failure of Publix to comply with state and federal mandates to maintain effective controls that ensure the legitimacy of opioid prescriptions.

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personally brief every registrant following its discovery of new patterns of diversion.\32\ Rather, as a participant in a highly regulated profession, Respondent's owner had an obligation to keep herself informed regarding regulatory developments which affected her profession. Cf. Holiday CVS, 77 FR at 62317 (citing United States v. Southern Union Co., 630 F.3d 17, 31 (1st Cir. 2010)

[222] Aug. 11, 2023, Lindsay Burckhalter, 30(b)(6), Deposition (hereafter "Burckhalter Dep."), 175; *see also* Brice Dep. at 334, 335.

[223] PUBLIX-MDLT8-00080521.

[224] Oct. 7, 2022, Chris Hewell, 30(b)(6), Deposition (hereafter "Hewell II Dep."), 313:16-314:25.

[225] Jacobson Dep., 312:23-313:8.

[226] Jacobson Dep., 314:3-14; Hewell II Dep., 314:13-25.

[227] Jacobson Dep., 314:3-14; PUBLIX-MDLT8-00082267-00082334 (P-PUB-0507) (Long chain email used to notify pharmacies of various suspicious providers).

[228] Jacobson Dep. 313:9-314:2

[229] Burckhalter Dep., 171-172.

[230] PUBLIX-MDLT8-00076600.

[231] *Id*.

G. Investigate, Resolve and Document Resolution of Red Flags

Consistent with best pharmacy practice and the warnings and agreements entered into with the DEA, the Chain Pharmacies' own policies recognize and require that when a controlled substance prescription has red flags, each flag must be resolved before that prescription is dispensed, and the pharmacist must document how that red flag was resolved.

The guiding elements establishing adequate due diligence are known to the Chain Pharmacies and generally are included in the Chain Pharmacies' policies and CSA recordkeeping requirements.[232] These common elements for adequate due diligence include:

1) The pharmacy must accurately identify and document all red flags raised by the prescription, patient, and prescriber;
2) The pharmacy must reasonably collect complete, relevant, and accurate information concerning each red flag;
3) The pharmacy must independently evaluate the collected information to determine whether the evidence is reliable and whether, as a whole, the evidence adequately resolves each red flag; and
4) Lastly, the pharmacy must clearly and explicitly document their evaluation of the evidence and their reasoning supporting their judgment to dispense or refuse to fill the prescription.

All four elements of due diligence are required: identification of all red flags, collection of all relevant information, evaluation of the information, and documentation of the reasons supporting the decision. Adequate due diligence will clearly explain to other pharmacy employees or regulators the concerns identified, the information evaluated, and the reasons for the decision.

Pharmacy practice standards of care, state board of pharmacy requirements, and the DEA guidelines provide that each prescription triggering a red flag must be resolved before the prescription is dispensed. Further, the resolution of that flag must be documented in order that, in the future, any person examining the prescription will know how the pharmacist resolved that red flag and why the medication was dispensed.

Documentation is critical for several reasons. It offers an explanation as to how the pharmacist resolved any red flags to allow for the dispensing of the prescription or why the pharmacist refused to fill the prescription and the steps taken afterwards. Documentation also affords the pharmacy the opportunity to review, audit, and investigate whether red flags are being identified and appropriately resolved, and it assists the DEA and state officials in the event there is a need to conduct an investigation related to diversion.[233]

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[232] KrogerMDL00002122 at 2150 ("If Red Flags are present the pharmacist must be able to resolve them and must document why they did.").
[233] May 13, 2021, John Aivazis Deposition (hereafter "Aivazis"), 316:12 – 317:1.

Joe Rannazzisi, former head of diversion control at the DEA, testified that:

> There has to be some documentation that you -- if you call the doctor, there's got to be documentation somewhere, either in a patient profile or on the prescription, that you called the doctor and why you resolved those red flags. That's -- during my time at DEA, we expected that. When we pulled prescriptions, that's what we were looking for….That doc doesn't necessarily have to be on the prescription. It could be in a patient profile. It could be in some type of medium within a computer, but there's got to be something there. It's a professional practice standard[234]

Recordkeeping is one of the CSA's primary means for preventing the diversion of controlled substances. *Grider Drug 1 & Grider Drug 2*, 77 FR 44,070, 44,100 (citing *Paul H. Volkman*, 73 FR 30,630, 30,644 (2008)). Under the Act, "every registrant . . . dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance . . . received, sold, delivered, or otherwise disposed of by him." 21 USC 827(a). DEA enforcement decisions have explained that "a registrant's accurate and diligent adherence to [its recordkeeping] obligations is absolutely essential to protect against the diversion of controlled substances." *Volkman*, 73 F.R. at 30,644. The DEA pharmacy handbook further emphasizes that complete and accurate recordkeeping "provide[s] accountability of all controlled substances from the manufacturing process through the dispensing pharmacy and to the ultimate user."[235]

DEA numbers are required to fill prescriptions for controlled substances, and accurate DEA numbers are necessary to ensure the prescriber maintains a license to prescribe substances. Such data deficiencies underscore Defendants' inadequate recordkeeping and failure to maintain effective abuse and diversion monitoring programs.

Publix failed to identify "dummy…" DEA numbers on several occasions prior to a prescription being filled.[236] DEA training guidance on whether a controlled substance prescription is legitimate or fraudulent was received by Publix.[237] In this training course, one method of checking for fraud is to check the physician's DEA number.[238] Despite having access to this course, prescriptions were issued with invalid DEA numbers. Additionally, Publix does not maintain a list of doctors whose DEA numbers have been revoked.[239] Pursuant to Publix's practice, a pharmacist is supposed to notify a supervisor if the pharmacist becomes aware that a physician's DEA number is invalid.[240] The supervisor is then supposed to investigate and communicate their findings to neighboring

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[234] CT3 Trial Testimony, Tr. 1590: 1-14, 10-14 (Oct. 12, 2021).
[235] DEA Pharmacy Handbook, 2020 Edition, p. 35.
[236] Smith Dep., 280:21-281-4.
[237] PUBLIX-MDLT8-00058475.
[238] *Id*. at 00058499.
[239] Nov. 16, 2022, Toan Do Deposition (hereafter "Do Dep."), 288:15-24.
[240] Do Dep., 270:8-23.

stores by email. This method is ineffective because it assumes that every recipient will read the email.

The need to monitor and document steps taken with respect to accessing of the PDMP is also important. The Defendants did not develop systems and programs to audit and monitor when the PDMP was being checked by their pharmacists and whether the pharmacy was in compliance with specific state mandatory PDMP checks.

While the Defendants' written policies eventually incorporated some of these important practices, the Defendants were slow to implement such requirements – most after 2012 and 2013.

Kroger

As a result of the 2005 DEA investigation, Kroger volunteered to implement a pharmacy compliance program.[241] This program included a pharmacy-wide controlled substance Standard Operating Procedure ("SOP") and training.[242] The purpose of the SOP was to "make CSA compliance as easy and efficient as possible" in light of Kroger's concern of recordkeeping violations.[243] This procedure covered several pharmacy obligations, such as general requirements for controlled substance prescriptions, corresponding liability and professional practice.[244] Yet, Kroger provided a list of only six criteria that may indicate that a prescription was not issued for a legitimate medical purpose.[245]

Beginning in 2012, Kroger emphasized the importance of "educating all pharmacy staff on known red flags of diversion" after recent DEA actions against other Chain Pharmacies. [246] Pharmacists were reminded of their "corresponding responsibility to dispense controlled substances only pursuant to a prescription issued in the usual course of the prescriber's practice for a legitimate medical purpose."[247] This guidance further instructed pharmacists to use "the state's prescription drug monitoring program and database."[248] Yet, Kroger's policy left pharmacists ill-equipped to adequately document the identification and resolution of red flags.

In November 2012, Kroger learned of DEA license revocation actions against a Cardinal Health distribution center, a Walgreens distribution center, and seven retail pharmacies, two of which

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[241] Press Release, Drug Enforcement Administration, Record 7 Million Dollar Settlement, Kroger Corporation establishes corporate wide compliance program (Oct. 24, 2005), https://www.dea.gov/press-releases/2005/10/24/record-7-million-dollar-settlement.
[242] KrogerSmithNMAG00003033.
[243] *Id*.
[244] *Id*. at 00003036.
[245] *Id*. at 00003091.
[246] FM 00028343.1.
[247] *Id.*
[248] *Id*.

were CVS stores and three of which were Walgreens stores.[249] In response, Kroger retained Buzzeo PDMA Consultants ("Buzzeo")[250] to perform a Suspicious Order Monitoring compliance audit.[251] As part of that audit, Buzzeo visited two Kroger pharmacies and interviewed pharmacists.[252] In his report dated March 12, 2013, Buzzeo found that

> Kroger line Pharmacists were not familiar with the term "suspicious order monitoring" and did not remember receiving any information from Kroger's corporate offices regarding prescription "red flags." Pharmacists appeared to know in general about their practice responsibilities but were not fully familiar with the term and meaning of "corresponding responsibility."[253]

Kroger did not begin documenting refusals to fill until very late. When it did so, it did not create a uniform system across all pharmacies. In furtherance of taking "proactive steps" to prevent diversion after DEA enforcement activity, Kroger required pharmacists to complete Controlled Substance Document ("CSD") forms for opioids in 2013.[254] However, this documentation was initially limited to prescriptions of Oxycodone, Methadone, and Hydromorphone.[255] Kroger did not include hydrocodone to this form until 2015 after hydrocodone was rescheduled as a Schedule II drug.[256] Pharmacists were also limited in their ability to view the CSD forms because they were hard copies.[257] Further, these forms were not utilized at all Kroger pharmacies, but only in approximately 100 of Kroger's 2,000 plus pharmacies.[258] The lack of consistency made Kroger's CSD form impractical to guard against diversion. In 2016, Kroger's policy required pharmacists to "DOCUMENT, DOCUMENT, DOCUMENT!" This included all refusals to fill a prescription.[259]

Today, Kroger's system permits pharmacists to document notes regarding red flags in the EasyFill Pharmacy Retail Network ("EPRN") system when filling a prescription received electronically.[260]

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[249] KrogerSmithNMAG00010074; KrogerSmithNMAG00010231.
[250] Ronald Buzzeo, R.Ph., is a former Deputy Director of the Office of Diversion of the DEA. KrogerSmithNMAG00003033 at 3035. He practiced as a pharmacist prior to beginning his law enforcement career as a Narcotic Investigator with the New York State Department of Health, Bureau of Narcotic Control. *Id*. After several years, he entered federal service with the Bureau of Narcotics and Dangerous Drugs, the predecessor agency to the DEA, where he served for 22 years until his retirement from federal service in 1990. *Id*.
[251] KrogerSmithNMAG00013075.
[252] *Id*. at 13079.
[253] *Id*.
[254] KrogerSmithNMAG00003336 (P-380858_00001).
[255] *Id*.
[256] KrogerSmithNMAG00004673
[257] Feb. 10, 2022, Blair Woolf Deposition (hereafter "Woolf Dep."), 85:13-86:21.
[258] KrogerSmithNMAG00005630 (P-30913_00001); McDermott I Dep. 355:1-357:7.
[259] FM 00028878.
[260] Jun. 10, 2022, Ryan Davis Deposition (hereafter "Davis Dep.") 57:15-59:16.

However, there is a lack of uniformity of the company's process to document red flags.[261] A pharmacist can provide comments in the patient, prescription or counseling notes.[262] Notes are also written "on the face of the prescription."[263] Nevertheless, Kroger's efforts to require documentation remain futile. Record retention policies at Kroger limit pharmacists access to notes.

Pharmacy controlled substance records should be used by pharmacists to prevent diversion. Documentation of prior prescriptions provides an overview of patient controlled substance use. Information related to the duration and strength of controlled substance prescriptions can assist pharmacists in resolving red flags. Retention of these records also permits a pharmacist to view previous CSD forms and notes regarding red flags and refusals to fill. Kroger failed to maintain these critical documents.

Beginning in 2007, Kroger issued a data retention policy that is reviewed on an annual basis.[264] For physical records, such as hard copy prescriptions, Kroger's 2019 policy instructs pharmacies to "securely maintain 2 years of records onsite."[265] After two years, the records are shipped to a storage vendor who will store the records for an additional nine years.[266] Essentially, pharmacists have access to these hard copy notes for a two year period of time. Notes retained at a storage facility are not readily available. Access to electronic prescription files at Kroger pharmacies are equally limited. Kroger maintains electronic prescriptions for only three years at the store.[267] This policy interfered with pharmacy staff's ability to effectively perform their duties. It also impeded continuity of pharmacy practice by limiting historical information as to the methods and practices utilized in Kroger pharmacies.

Kroger employees, including those charged with compliance responsibilities, pharmacy managers, and pharmacists, use email to communicate a wide variety of important business and patient safety matters. Some examples include corporate guidance on due diligence investigations, identifying suspicious prescriber or patient behavior, or providing critical information concerning fraud or diversion. Access to historical email records is very limited, however, and largely dependent upon subjective judgments made by individual Kroger employees with effectively no guidance from Kroger's corporate-level leadership. Prior to 2012, Kroger's document retention policy maintained emails for 60 days.[268] After 2012, this time period was reduced to only 30 days.[269] The emails are

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[261] *Id*. at 59:5-7 ("My partner that was working next to me may have a different process of documenting than I would as well.").
[262] *Id*. at 60:2-61:11.
[263] *Id*. at 57:15-58:14.
[264] Jul. 15, 2022, Rachel Divincenzo Deposition (hereafter "Divincenzo Dep."), 15:2-6; KROGERWVAG00000827 (P-KRO-0615).
[265] KROGERWVAG00000827 at 0000030 (P-KRO-0615) at pg. 4.
[266] *Id*.; Divincenzo Dep. 32:5-17.
[267] KROGERWVAG00000827 at 0000034
[268] Divincenzo Dep. 67:7-3
[269] *Id*. at 31:14-22.

then automatically soft deleted and recoverable for 28 days after that.[270] Once the total of 58 days are up, the emails are permanently deleted. Emails may be stored for longer than 30 days only if the custodian determines that there "is a business need" to maintain the email and takes the affirmative step to save the e-mail by placing the email in a "KeepIt" folder.[271] Kroger's email retention policies do not delete emails in an employee's "KeepIt" folder, but also provide no guidance as to what should be placed in the folder other than instructing the employee to preserve emails constituting a "business need" or otherwise required to be kept under a separate Kroger policies (none of which address email concerning suspicious prescriber or patient behavior).[272] This policy provides for arbitrary decision making on behalf of the custodian and can lead to confusion. Many employees were not even made aware of the Keepit folder, and Kroger provided no guidance as to what constitutes a "business need."[273] This retention policy which has the potential to impede compliance investigations and safe patient care because it results in so much information being lost. I am not aware of another chain pharmacy in the country whose which provides such a limited document retention policy.

A pharmacist may only dispense a controlled substance that is issued for a legitimate medical purpose.[274] Indeed, a pharmacist must dispense the prescription in the usual "course of professional practice."[275] The obligation to dispense legitimate controlled substance prescriptions extends to Kroger.[276] Red flags are widely recognized as customary practice in pharmacies. As previously discussed, Chain Pharmacies, acknowledged the importance of the recognition and resolution of red flags. In particular, Kroger identified signs of diversion in its 2005 SOP that was created in response to recordkeeping violations.[277] This list expanded in 2012 following DEA investigations and actions against other Chain Pharmacies.[278]

Kroger is aware of its duty to guard against diversion. Nevertheless, Kroger's record retention policies make documentation of the identification and resolution of red flags inaccessible. Detection of diversion is an obligation that all Chain Pharmacies have. Kroger disregarded this duty by implementing a document retention policy that destroyed records relevant to whether its pharmacists performed adequate due diligence.

Publix

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[270] *Id*. at 78:22-79:17.
[271] KrogerWVAG00000695 at 00000696.
[272] Divincenzo Dep. at 31:14-32:1; *see, e.g.,* Kroger-MDL00034579 at 80.
[273] Jan. 23, 2023, Betsy Wright Deposition (hereafter "Wright Dep."), 41-42; see generally Divincenzo Dep. at 70-73.
[274] 21 C.F.R. 1306.04(a)
[275] 21 U.S.C. § 829; 21 U.S.C. § 1306.06.
[276] 21 C.F.R. 1306.04(a).
[277] KrogerSmithNMAG00003033; Kroger-MDL00031079.
[278] KrogerSmithNMAG000348.

Publix did not issue guidance to its pharmacists regarding the identification of red flags until 2012.[279] Even then, the policy did not require documentation of red flags or other forms of due diligence unless the pharmacist specifically consulted Georgia's PDMP.[280] Even after that guidance was issued, however, Publix failed to adequately communicate it to its pharmacists. Jillanne Smith testified that new hires were provided with the written guidance, but there was no specific training on identifying and resolving red flags until 2018.[281] Publix did not monitor whether pharmacists or technicians received or reviewed this guidance. Shannon Brice, a pharmacist with a 25 year career at Publix, had never seen the guidance on red flags until preparing for her deposition.[282]

Until at least 2019, Publix did not require documentation of red flags but rather "recommended" it.[283] Controlled substance guidance also suggested that a note should only be left for an existing customer in limited circumstances where a pharmacist determines that the prescription is suspicious after checking PDMP.[284] Later guidance required that all red flags be resolved prior to filling a controlled substance prescription and "to document" what red flags were cleared.[285] Particularly, "if a pharmacist agrees to fill at-risk medication combinations, high MME, and/or RX with Red Flags" it is recommended that the pharmacists document how the red flags were cleared.[286] Publix reasoned that "[i]f you don't document, then there is no proof the conversation, the consultation, or the clearing of red flags took place."[287] However, Assistant Pharmacy Manager, Joseph Wells described this process as a "little bit difficult" or "self-explanatory"[288] Publix recognized DEA guidance stating that "the presence of ONE red flag that cannot be cleared is enough to refuse to fill a prescription."[289] Therefore, if a pharmacist is unable to clear a red flag and refuses to fill a prescription, "documentation needs to be done stating what red flags existed and that they could not be cleared."[290] In addition to the nonconformity of Publix's documentation policy, some employees are unclear or simply don't recall whether there even is a policy in place.[291]

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[279] Smith Dep., 386:9-390:16; *compare* PUBLIX-MDLT8-00023196 (Smith Ex. 15) (Red flag guidance not included in Publix pharmacy guide dated April 27, 2012), *with* PUBLIX-MDLT8-00027405 at 00027438 (Smith Ex. 16) (July 25, 2012 guidance was the first that included red flags—though without calling them "red flags"
[280] PUBLIX-MDLT8-00027405

[282] Brice Dep., 44:5-45:20.
[283] PUBLIX-MDLT8-00077099; Smith Dep., 375:7-25.
[284] PUBLIX-MDLT8-00067275 at 00067294
[285] PUBLIX-MDLT8-00149649 at slide 4 (P-PUB-0728) (Wells Ex. 9).
[286] PUBLIX-MDLT8-00149649 at 00149658 (P-PUB-0728) (Leonard Ex. 10).
[287] PUBLIX-MDLT8-00149649 at 00149667 (P-PUB-0728) (Wells Ex. 9)
[288] Jun. 25, 2023, Joseph Wells Deposition (hereafter "Wells Dep."), 241-243.
[289] PUBLIX-MDLT8-00149649 at 00149658 (P-PUB-0728) (Leonard Ex. 10).
[290] *Id*.
[291] Smith Dep., 374:12-375:25; Brice Dep., 335:6-13 (Pharmacy Manager "not aware" if there is a requirement that pharmacists document due diligence done in resolution of a red flag).

In 2021, Publix's opioid task force team, comprised of three pharmacists, gave a presentation that stressed the importance of documentation: "Document, Document, Document. If you don't document, then there is no proof the conversation, the consultation, or the clearing of red flags took place."[292] Notes regarding red flags can be placed in the field for transaction notes, counseling notes, prescriber notes, and patient notes in EnterpriseRx.[293] However, there is no uniform policy regarding where to document, making it difficult to know where a note may be located.[294] Pharmacists must click on multiple individual note fields to check for prior documentation.[295]

In 2013, Paul Hines, "the main communication agent for Publix with the DEA in the pharmacy department" met with the DEA Diversion Program Manager and discussed the corresponding responsibility to dispense only prescriptions that are issued for a legitimate medical purpose.[296] This obligation includes the investigation of red flags that "should not be ignored."[297] Publix was aware of the significance of red flags and its duty to prevent diversion. Yet, practical guidance in the pharmacy remained inadequate.

Access to and review of dispensing data is imperative to ensuring compliance with federal and state regulations. Prior to 2011, Publix did not implement a document retention policy for corporate records.[298] Employees determined whether to keep documents based on what was "relevant for business and legal purposes."[299] In approximately 2011, record retention policy for dispensing data at Publix was set at ten years.[300] Until 2019, Publix purged dispensing data every day.[301] Once the dispensing record was purged, it was deleted permanently.[302] Since Publix does not block the prescriptions of a suspicious provider, the pharmacy relies heavily on email notifications and notes written on a prescription by a pharmacists.[303] Publix's policies and procedures are inadequate to guard against diversion.

H. Corporate Oversight Failures

Every pharmacy maintains dispensing data which could and should have been utilized by the Defendant pharmacies to prevent diversion. Dispensing data should have been reviewed by each corporate defendant to identify patterns of diversion and to create policies and procedures and

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[292] PUBLIX-MDLT8-00149649
[293] Hewell II Dep, 302:18-304:7.
[294] *Id*. 315:16-316:16.
[295] *Id*. at 304:8-308:8.
[296] Dec. 6, 2022, Fred Ottolino Deposition (hereafter "Ottolino Dep."), 41:20-41:22; PUBLIX-MDLT9-00066086 (P-PUB-0248).
[297] *Id*. at 00066087.
[298] Sept. 30, 2022, Chris Hewell Deposition (hereafter "Hewell I Dep."), 137:17-138:21.
[299] Hewell I Dep., 138:9-21.
[300] Hewell II Dep., 316:18-317:5, (hard copy prescriptions are also limited to a 10 year retention period unless there is a litigation hold); P-PUB-0138 (Hewell 30(b)(6) Ex. 4).
[301] P-PUB-0138 (Hewell 30(b)(6) Ex. 4).
[302] Hewell I Dep., 68:10-16.
[303] Ottolino Dep., 1159-13; See e.g., PUBLIX-MDLT8-00086381.

training materials which proactively identified patterns of diversion. Defendants should have used the information gleaned from that proactive analysis to inform their pharmacy staff of these patterns and to develop policies, procedures, and training materials for its pharmacies.

Based on my review of documents and testimony, Defendants possessed dispensing data and other information collected at a corporate level. Defendants had access to extensive and detailed prescription data and other information. For example, Kroger and Publix each collect dispensing data and store it in centralized data warehouses. Responses and documents from Defendants indicate that Kroger and Publix also had access to third party data.

As former DEA Diversion Investigator, Demetra Ashley testified, dispensing data for most large chain pharmacy companies is kept in central locations and retrievable through dispensing data databases.[304] These databases, if accessed properly, could do many of the same things as a PDMP, such as identify red flags associated with the data.[305] Ashley testified that it "would be reasonable to expect the pharmacies to access their own databases to look for red flags."[306] She further testified that "if a pharmacy company is being vigilant in the face of a raging prescription opioid pill epidemic, access to that database of information would be important."[307] This testimony is consistent with what should have been the pharmacy industry practice throughout the period of the epidemic. In fact, most of the chain pharmacy defendants developed a number of programs at the corporate level to analyze their dispensing data for prescribers, patients, and pharmacies potentially engaged in diversion, but they did not do so in a timely manner and did not share that information with their pharmacists. Publix did not even attempt to develop such programs until after 2018.

Many of the red flags described in this report are easier to identify through the use of computer-generated calculations. For instance, it would be far easier and more accurate for information from the corporate dispensing program to alert a pharmacist if multiple patients present prescriptions for the same combination of drugs at different pharmacies within the corporation. Likewise, a program could have been written to calculate the distance between the patient and the prescriber or the patient and the pharmacy. If the distance exceeds 25 miles, the pharmacy dispensing program could issue a warning or alert to resolve the distance flag before the prescription is filled. Similarly, the software could have alerted pharmacists to known red flag combinations of drugs such as an opioid and a benzodiazepine. This is particularly useful when the prescriptions have been filled on different days, for different days' supply and at different pharmacies in the same chain. As another example, Chain Pharmacies could implement policies and procedures to alert refusals to fill for certain prescribers or prohibit filling for those prescribers altogether. Defendants should have used the information available to them at the corporate level to guard against diversion. The evidence I have seen indicates that they did not.

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[304] Mar. 11, 2021, Demetra Ashley Deposition (hereafter "Ashley Dep."), 115:9-14.
[305] *Id.* at 115:16-116:4.
[306] *Id*. at 132-34.
[307] *Id*. at 10:42.

Kroger

Examining dispensing data can identify patterns of diversion. Kroger could obtain data related to the filled prescriptions on a corporate level and on a store level basis.[308] Further, Kroger has the ability to view prescriber activity at a corporate level.[309] This data is limited due to the lack of access each individual stores access to all prescriber activity.[310] Individual pharmacies are unable to view dispensing data outside of their store.[311] However, Kroger had access to IMS/IQVIA and failed to utilize this data adequately.[312]

In 2000, Kroger began selling its prescription data to IMS/IQVIA.[313] In exchange, IMS data was accessible to Kroger. Applications, such as the Controlled Substance (CS) Rating tool provided Kroger with the ability to monitor controlled substance use. This feature "leverages outlet purchasing and outlet dispensing information along with geographical comparative data to provide visibility to prescription activity for certain controlled substances."[314] As a result, prescribing habits of doctors became readily available to Kroger's compliance department. The available data related to the identification of stores which filled prescriptions for a specific prescriber and the number of prescriptions filled appeared in the reports.[315] The CS Ratings tool generates reports that alert to red flags, such as distance, drug combinations, days' supply, and patient cash payment.[316] Patient drug analysis provided in the reports can identify suspicious prescribing behavior. Yet, when filling a prescription, a Publix pharmacist does not have access to these reports.[317] Pharmacists are limited to the data of a doctor's prescribing habits at their individual pharmacy.[318]

After the DEA investigations in 2012, Kroger issued a communication regarding a new EPRN edit that would "prevent filling controlled substance prescriptions written by prescribers that have been identified as having prescribing practices that raise concerns."[319] Kroger provided that it "may review prescriptions and quantities of controlled substances purchased and dispensed at particular pharmacies as well as the prescribing practices of certain prescribers."[320] This data was reviewed

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[308] McDermott II Dep., 63:12-65:19.
[309] *Id*. At 65:3-66:4.
[310] *Id*. At 66:5-67:23.
[311] *Id*. At 67:11-23.
[312] KrogerSmithNMAG00011364; Kroger-MDL00034096. *See also,* Sept. 9, 2022, Mercury Williams Deposition (hereafter "Williams Dep.") and exhibits.
[313] *Id.* at Williams Exhibit 9, Kroger_MDL00034103; *See also,* Williams Exhibit 13, Kroger-MDL00034078
[314] Kroger-MDL00034096 at 00034100.
[315] KROGERMDL00000994 at pg. 2 (P-KRO-0523); Davis Dep. at 338:1-6.
[316] KROGERMDL00000994 at pgs.2-5 (P-KRO-0523).
[317] Davis Dep. at 331:8-13; 339:20-340:14.
[318] *Id*. at 340:15-18.
[319] KrogerSmithNMAG00008329.
[320] *Id*.

by corporate after receiving a concern at the division level or by using Nine Box reports for certain stores.[321]

Kroger relied heavily on its wholesaler, Cardinal Health, in identifying stores to investigate. A 9-box report is a monthly report sent by Cardinal that identifies "outlier pharmacies for oxy, hydro, and methadone based on dosage units shipped to total prescription count."[322] "When a store is identified on a 9-box report it indicates that their dispensing pattern of the drug family in question falls significantly above the majority of stores with similar total prescription counts."[323] Upon receiving such a report, Kroger was supposed to conduct its own due diligence activities through a professional audit to "assess controlled substance dispensing trends and potential Red Flag dispensing concerns."[324] No similar investigation was performed on stores which were not identified by Cardinal. Out of all the stores Kroger operates in the state of Georgia, only one pharmacy triggered a nine-box report from Cardinal.[325] The other pharmacies in Georgia were not investigated by Kroger pursuant to this program. Given the staggering volume of opioids dispensed by Kroger in Georgia, the overwhelming numbers of people suffering from opioid use disorder and the heightened risk of diversion in the state, the failure of Kroger to investigate its pharmacies demonstrates the failure in Kroger's systems to identify and prevent diversion.

Kroger's corporate analyst ran reports based on the Cardinal's 9-box report. The reports provided information such as top prescribers, prescriber patterns, cash pay, and drug cocktails and were forwarded to the appropriate division.[326] However, there was no standard set of analysis, rules, or a checklist to go by.[327] The data collected in the audit enabled the "division team to work with their stores to do a deeper dive into that store's data to understand if there were any potential concerns in the dispensing patterns for that store."[328] Even though Kroger had tools at the Corporate office to guard against diversion and investigate stores of concern, Kroger failed to utilize these tools in all pharmacies. Today, Kroger does not even have a report that it runs to flag pharmacies of concern.[329]

Kroger failed to address diversion on a store level basis as well. Information related to refusals to fill and CSD forms are not readily available to other pharmacies. The refusals were simply placed in a "filing cabinet for up to two years."[330] Further, there was no data analysis of the refusals.[331]

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[321] McDermott I Dep., 175-178:17.
[322] KrogerMDL00002558 at 00002563.
[323] *Id*. at 00002564.
[324] *Id*. at 00002567.
[325] *See e.g*., Kroger-MDL00028231.
[326] McDermott II at 227:5-229:2.
[327] *Id*. at 232:13-233:5.
[328] *Id*. at 225:2-226:2.
[329] *Id*. at 237:7-12.
[330] Feb. 16, 2022, Jeanie Goodrich Deposition (hereafter "Goodrich Dep."), 76:13-23.
[331] *Id*. at 78:14-18.

CSD forms are attached to the prescription with only a vague description within EPRN.[332] Kroger's controlled substances policies are insufficient to prevent diversion.

In June 2015, DEA Deputy Assistant Administrator, Joe Rannazzisi, attended Kroger's Pharmacy Merchandiser meeting and explained what the DEA looks at.[333] The committee also discussed the NABP's document regarding "Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances."[334] By December 2015, the PCC was notified of the "increase in the number of overdoses in Kroger stores."[335] Kroger passed up opportunities to refine procedures.

As part of its compliance program efforts, Kroger implemented a pharmacy audit program. Kroger conducted internal studies beginning in 2006 and implemented an external study by LPI, a third-party vendor, in 2009.[336] Internal audits focus on compliance with Kroger's controlled substance SOP that was initiated following DEA investigations. At least four times a year, the Pharmacy Manager and Store Manager conduct an audit that is "designed to be a quick 15 minute review."[337] Audit findings are documented on a twenty-seven question form were the auditor can indicate either "YES" or "NO" and a comments section.[338] None of the questions listed on the audit form inquire about a review of controlled substance prescriptions.

The second internal audit is completed by the Pharmacy Coordinator who conducts a "detailed" audit once a year.[339] During the annual review, the auditor reviewed controlled substance prescriptions to review whether it contained the patient's name and address; the prescriber's name, address, and DEA number; the named and strength of the drug, the quantity ordered; the name of the prescriber's agent for phone-in prescriptions; directions of use; physicians signature for CII scripts; date of issuance; and the initials of the dispensing pharmacist. Despite accessing this data on an annual basis, the auditor does not check to determine whether the pharmacists exercised due diligence in filling the controlled substance prescriptions or otherwise appropriately exercised corresponding responsibility. Kroger's internal audits do not include a review of pharmacist's controlled substance dispensing.

External audits performed by LPI were similarly deficient in reviewing pharmacists' due diligence. In 2009, Kroger outsourced pharmacy compliance audits to LPI to perform audits on "10% of Kroger's retail locations."[340] This audit includes a review of compliance with Kroger's controlled substance SOP, "on-hand inventory counts of specific SKU's identified by Kroger Management

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[332] McDermott I at 210:20-211:14.
[333] KrogerSmithNMAG00010239 at _0004.
[334] *Id*.
[335] *See* December 2015 PCC Minutes at bates KrogerSmithNMAG00012983 at 00012988.
[336] McDermott I, 230-233; 235.
[337] KrogerSmithNMAG00007196 at 00007197.
[338] *Id*. at 00007201-02.
[339] *Id*. at 00007197.
[340] KrogerSmithNMAG00008281 at 00008307; McDermott I, 250:10-13, (The percentage of stores audited increased to 15 percent at one point in time).

and a review/training of the results with in-store pharmacy mgmt."[341] Audits performed by LPI were similar in format to the audits performed by the Pharmacy Coordinator.[342] LPI also reviewed prescriptions to determine whether it contained data, such as patient name and address.[343] Yet, this audit did not review whether a pharmacist properly resolved red flags prior to dispensing a controlled substance. In fact, Kroger the LPI auditors are not licensed pharmacists or pharmacy technicians, and the LPI audits did not in any way address whether or not a pharmacist was correctly exercising corresponding responsibility for reviewing red flags.[344]

Kroger's audit initiatives do not ensure its pharmacists are complying with its obligations under the CSA or state law concerning the appropriate dispensing of controlled substances. Internal and external audits fail to assess whether a pharmacist properly exercise their corresponding responsibility and whether they appropriately identified and resolved a red flag prior to dispensing.[345]

Publix

As previously mentioned, diversion analysts at Publix were only hired beginning in 2018.[346] During this time, Publix began a centralized effort to run dispensing data analytics at a corporate level.[347] Publix had access to IQVIA data beginning in 2010.[348] "On a daily basis, IQVIA is provided a data extract from Publix's EnterpriseRx pharmacy dispensing data by the" Pharmacy Analytics and Compliance Team ("PACT").[349] Publix recognized that it was their "responsibility to monitor the dispensing patterns associated with controlled substances."[350] Prior to approximately April 2018 and March of 2019, Publix did not utilize their data to identify signs of diversion, such as dispensing patterns.[351] Its efforts at centralization of controlled substance compliance initiatives such as diversion analytics red flag training was in its infancy stage in November of 2018.[352]

Discussions about acquiring the IQVIA CS Ratings tool began in 2018. This application would allow Publix to leverage "outlet dispensing information along with geographical comparative data

[341] KrogerSmithNMAG00008281 at 00008307.
[342] McDermott I, 248:15-22.
[343] *Id*. at 252:11-253:3.
[344] Feb. 2, 2023, Jeff Loesch Deposition (hereafter "Loesch II Dep."), 110:4-23.
[345] *Id*. at 262:2-19.
[346] Hewell III Dep., 149:24-150:2.
[347] Smith Dep., 250:6-23.
[348] PUBLIX-MDLT-00098380 at 00098383.
[349] P-PUB-0140 at p. 11.
[350] PUBLIX-MDLT8-00079714 at 00079715 (P-PUB-0371).
[351] Smith Dep., 98:3-18.
[352] PUBLIX-MDLT8-00079714-16 (P-PUB-0371).

to provide visibility to prescription activity for certain controlled substances."[353] However, the IQVIA CS Ratings tool was not acquired until 2021.[354]

The EnterpriseRx system was put into place before 2010, as the dispensing system for all Publix pharmacies.[355] An electronic record is created at Publix once the prescription is scanned.[356] This electronic data is housed in Publix's On-line Transaction Processing (OLTP) database and made available to every Publix pharmacist in each store.[357] Pharmacy support associates, technicians, and supervisors also had access to the information stored in OLTP through the EnterpriseRX user interface.[358] Despite the accumulation of this data, pharmacists are unable to retrieve data related to the highest prescriber in their zip code and are limited to viewing a prescriber that is already recorded in the system.[359] Only two years' worth of transactional data is available for pharmacists to view.[360] Consequently, pharmacists are limited to only two years of notes related to refusals to fill that are documented on a prescription.[361]

I. Corporate Policies Failed to Make PDMP Checks Mandatory.

As described above, PDMPS provide valuable information to aid dispensing decisions.

Information from the National Association of Boards of Pharmacy ("NABP") also describes more than 40 states as having signed "a memorandum of understanding with NABP to participate in NABP PMP InterConnect®" as of May 18, 2016.[362] Presently, all states, with the exception of Missouri, which enacted county-wide agreements with NABP, have operational and interconnected PDMPs. As described below, however, pharmacists faced time-pressure from metrics Defendants imposed. Meanwhile, Defendants' policies for years failed to require that pharmacists check PDMPs before dispensing opioid prescriptions, despite clear recognition of the critical role that such PDMPs play in fighting diversion.

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[353] PUBLIX-MDLT-00098380 at 00098383.
[354] P-PUB-0182; Hewell II Dep., 359:22-360:5; PUBLIX-MDLT-00098380 at 00098383.
[355] Hewell II Dep. at 205:19-206:18.
[356] *Id*. at 204:1-22.
[357] *Id*. at 208:19-212:15.
[358] *Id*. at 219:25-221:18.
[359] *Id*. at 216:1-218:10.
[360] *Id*. at 292:4-293:18.
[361] *Id*.
[362] https://nabp.pharmacy/members/pmp-interconnect/#:~:text=NABP%20PMP%20InterConnect%C2%AE%20facilitates,diversion%20and%20drug%20abuse%20nationwide.

In 2012, the Ohio Board of Pharmacy approached Kroger with an opportunity to participate in a pilot program integrating PDMP into Kroger's dispensing system.[363] In exchange for this effort, Kroger received a grant in the amount for fifty-thousand dollars.[364] Kroger did not launch the PDMP integration in its Ohio pharmacies until July 29, 2015.[365] The contract process for PDMP integration in Georgia Kroger pharmacies did not begin until 2017.[366]

The PDMP integration greatly assisted pharmacists with workflow and decreased the amount of time it would take pharmacists to review the PDMP. Pharmacists can access "information about the patient" and know where else the patient is "getting prescriptions and what other prescribers or pharmacies" the patient is visiting.[367] Nevertheless, Kroger did not monitor whether PDMP was being used.

After several DEA actions, Kroger issued guidance on red flags and PDMP checks. However, Dallas Division Leader, Jeffrey Loesch, testified that in his view not every red flag needs to be resolved before a controlled substance is dispensed.[368] Kroger did not require pharmacists to check PDMP databases prior to 2013. At that time, Kroger instructed its pharmacists to "check, review and print a report from the state Controlled Substance database (PDMP)" and "attach a hard copy."[369] Utilizing PDMP would allow a pharmacist to access "information about the patient" and know where else the patient is "getting prescriptions and what other prescribers or pharmacies" the patient is visiting.[370]

In 2013, Publix issued a PDMP policy requiring that "all Publix Pharmacists should at a minimum create a personal account and use the website database to identify whether or not dispensing certain controlled substance prescriptions is appropriate."[371] Publix does not maintain an electronic record of whether pharmacists are referencing PDMP when filling a prescription.[372] Further, it is "not the norm" for Publix pharmacists in Georgia to check PDMP for each controlled substance prescription.[373] Checking PDMP can provide critical information that can assist a pharmacist in preventing diversion. Yet, Publix pharmacists must manually enter their email and password to access PDMP due to the lack of PDMPs integration into Publix's dispensing system.[374]

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[363] BOP_MDL1993662 (Griffin Exhibit 17).
[364] Kroger-MDL00171823 at 00171824.
[365] BOP_MDL1993662 at 1993663 (Griffin Exhibit 17); Kroger-MDL00163667.
[366] Kroger-MDL00163664 at 00163666.
[367] Jun. 23, 2022, Laura Raney Deposition (hereafter "Raney I Dep."), 145:25-146:16.
[368] Jul. 7, 2022, Jeffrey Loesch Deposition (hereafter "Loesch I Dep."), 81:1-24.
[369] KrogerSmithNMAG00009652-54.
[370] Raney I Dep. at 145:25-146:16.
[371] PUBLIX-MDLT8-00006178 at 00006218.
[372] Hewell II Dep. at 340:22-341:3.
[373] PUBLIX-MDLT8-00074321 (P-PUB-0599) (Plaintiff's Ex. 14).
[374] PUBLIX-MDLT8-00115817 at 00115818 (P-PUB-0719) (2021 pharmacist request to integrate PDMP into EnterpriseRx or save time "without manually entering email and pw about 30 times per day.").

J. Corporate Performance Metrics Undermined Compliance.

Prime metrics that are collected, analyzed, and enforced as evidence of the overall corporate control of the individual pharmacies and pharmacists are performance measures relating to the dispensing of prescriptions, customer wait times, and sales. The information I reviewed clearly demonstrated that the Defendants collected data from the individual pharmacies and analyzed the data to determine and monitor those performance metrics.

Publix uses a strategic dashboard to measure performance objectives. Each objective is measured by using a Green, Yellow, and Red rating during the annual retail bonus plan review.[375] Since at least 2011, Publix's quarterly retail bonus plan is based on 15% of the store's total performance, approximately 40% of the store's script count, and about 45% on department profitability.[376]

Other performance evaluation factors include the 10-foot, 10-second rule, minimal customer wait times, and increased vaccinations.[377] These performance goals leave pharmacists overworked. It was previously noted that "many feel as though they are completely unattainable or out of their control."[378] The metrics that are evaluated at Publix are based on profitability with key performance indicators that are focused on net profits and sales goals.[379] Metrics such as "shrink" that measures "idle" inventory includes opioids.[380] Meanwhile, concerns of inadequate staffing at Publix have been raised by pharmacists and customers alike.[381] Pharmacists perform many important tasks that impact patient safety. One customer in Cobb County expressed concern about the ability of a pharmacist "to fill prescriptions, run a register, answer the phone, leave from behind the counter to show a customer where a product is located, and explain how the prescription is to be taken or used" without the assistance of additional staff.[382]

If a customer chooses to wait for a prescription, Kroger prioritizes the customer in EPRN.[383] Kroger also utilizes Reportal, an interactive dashboard, that enables a pharmacist to view customer wait time.[384] As an incentive to keep customer wait times low, Kroger pharmacies have based up to 25% of the pharmacy bonus on a customer wait time of less than 20 minutes.[385] The clock begins during pre-verification when the product is counted and ends at the final verification or when the

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[375] PUBLIX-MDLT8-00060490.
[376] PUBLIX-MDLT8-00060787; PUBLIX-MDLT8-00059249.
[377] PUBLIX-MDLT8-00115010 at 115040.
[378] PUBLIX-MDLT8-00115837.
[379] P-PUB-0462 (King Ex. 19).
[380] King Dep., 314:6-13; P-PUB-0464 (King Ex. 20).
[381] PUBLIX-MDLT8-00092608-09 (P-PUB-0711) (King Ex. 38); PUBLIX-MDLT8-00092606 at 00092607 (P-PUB-0546) (King Ex. 39) (customer reporting that there is "[n]ot enough staff in the pharmacy."); Brice Dep., 156:10-157:16.
[382] PUBLIX-MDLT8-00092608-09 (P-PUB-0711) (King Ex. 38).
[383] Kroger-MDL00027117 at 00027125.
[384] Davis Dep. at 141:1-7; 142:1-10.
[385] FM00028774; KrogerMDL00000083 at 00000099.

script is good to go out the door.[386] Notably, a pharmacist's assessment of red flags also occurs during this timed period. This practice creates unsafe distribution of controlled substances where pharmacists are required to weigh in customer satisfaction over consumer wellbeing.

Other time-based metrics, in addition to customer wait time, were used at Kroger to evaluate its pharmacies and pharmacists. A Kroger supervisor may view timing metrics for the prior week down to a tenth of a second.[387] These metrics can include pharmacists' due diligence responsibilities such as pre-verification, drug utilization review, and verification.[388] This process included the verification of prescriptions that included controlled substances.

Kroger prioritized customer loyalty and profitability. Data collected by Kroger showed that customers who purchased narcotics had a much higher rate of loyalty and spending.[389] Kroger tied pharmacist bonuses and other financial incentives to the number of prescriptions filled, including prescriptions for controlled substances. The DEA expressed concerns that bonus incentives for dispensing controlled substances could "lead to bad pharmacist decisions because they know they get will something out of filling scripts."[390] The added direct impact on salary and bonus if metrics were not met further overrode pharmacists' professional judgment and legal responsibilities.

Near the end of 2012, Kroger instructed pharmacies to remove incentives in the bonus program for controlled substance prescriptions.[391] This policy change came after DEA activity regarding disciplinary action against other chain pharmacies due to excessive controlled substance prescriptions.[392] Unlike CVS, Walgreens, Wal Mart, and Kroger, Publix continues to include controlled substances in script count, volume, and store profitability measures for the purpose of pharmacist and pharmacy leader bonus calculations.[393] Publix's own pharmacist, Shannon Brice, testified that including controlled substances in prescription counts for the purpose of pharmacist or pharmacy leader bonus calculations was "inappropriate"[394] yet at Publix, the more controlled substances that a Publix pharmacy fills, the more money Publix pharmacists make.[395]

As a result of the findings in Ohio Board of Pharmacy workload survey, Kroger decided to conduct a survey of their employees.[396] The internal Kroger pharmacist survey reported that "88% of respondents disagreed that there is adequate staffing in the pharmacy."[397] In addition, "88% of

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[386] Davis Dep., 142:14-143:14.
[387] *Id*., 137:22-138:8.
[388] *Id*. 137:5-12.
[389] Kroger-MDL00147048 at 00147050 (P-KRO-1146).
[390] WMT_MDL_000233226 (NACDS DEA Compliance Working Group Meeting Summary (Feb. 12, 2013).
[391] KrogerSmithNMAG00010074 at 00010075.
[392] *Id*. at 00010074.
[393] PUBLIX-MDLT8-00059249
[394] Brice Dep. 339:2-341:10.
[395] Burckhalter Dep. at 176.
[396] Aug. 29, 2023, Laura Raney Deposition (hereafter "Raney II Dep."), 190:7-191:2.
[397] KrogerWVAAG00024849.

pharmacy associates who responded to the survey agreed that their work causes them to be physically and emotionally exhausted."[398] As a result only "11% agreed to the question 'I feel the workload allows me to get everything done in a safe, satisfactory manner."[399] Kroger recognized the alarming results from its survey and launched a focus group in November 2021 of about sixty pharmacists to understand common themes. One theme Kroger sought to understand was the impact of pharmacy metrics on patient safety.[400] "Pharmacists [at Kroger] feel caught in the middle of corporate expectations to meet metrics and customer demands for promised services."[401] One pharmacist from the study group provided feedback that "they thrive on being busy and being useful, but when metrics are 'a sea of red,' it feels like failure."[402] The metrics utilized at Kroger fail to support patient safety. Findings from the focus group revealed that the pharmacists struggled to recall a Kroger metric that facilitated patient safety.[403] On the contrary, "chasing metrics [is] just another distraction from patient safety."[404]

Kroger's 30(b)(6) corporate witness, Laura Raney, stated that Kroger agrees that hearing from "pharmacy associates is important to providing the best patient and associate work experience."[405] Due to a quality improvement project initiated by a pharmacy resident, Kroger launched a patient safety survey in 2018.[406] This survey yielded "very concerning" comments from respondents.[407] The top trend in the open comment section include concerns regarding hour cuts/staffing, increased workload, and training.[408] Out of the 930 respondents, 228 provided written comments.[409] The responses ranged from concerns of feeling "pressure to keep wait times low and rush as much as possible" and demands to meet metrics at the risk of "patient safety for the sake of saving money on labor".[410] Many respondents indicated that Kroger focused on metrics at the expense of patient safety.[411] Respondents communicated their concern of patient safety, making Kroger well aware of the risks created by metric demands.[412] Further, the workload and inadequate staffing place

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[398] *Id*.
[399] *Id*.
[400] Kroger-MDL00214492; Kroger-MDL00214490 at MDL00214490.
[401] Kroger-MDL00214473 at 00214475.
[402] Kroger-MDL00214473 at 00214477.
[403] Kroger-MDL00214473 at 00214487.
[404] *Id*.
[405] Raney II Dep., 97:23-98:6.
[406] *Id*. at 100:7-19.
[407] Kroger-MDL00153713.
[408] KrogerWVAG00024853 at 00024858 (Raney Ex. 4).
[409] Kroger-MDL00153729; Kroger-MDL00153715.
[410] Kroger-MDL00153715 at 00153718, 00153716
[411] Kroger-MDL00153715 at 00153720 (Kroger is "constantly putting 100% of their focus on metrics."); 00153724 (one respondent requesting "less emphasis" on "profit metrics"); at 00153727 (Kroger places "too much emphasis on meeting metrics and not enough on patient safety").
[412] Kroger-MDL00153715 at 00153719 ("Increasing demands (metrics, script count, additional programs, etc.) with decreasing tech/pharmacist help can/will eventually lead to patient safety issues.").

patient safety at risk.[413] Several respondents indicated that inadequate staffing leads to pharmacists being overworked and unable to take the time to provide safe care to patients.[414] Pharmacist and technician training was also a point of concern for respondents.[415] Even with this insight into working conditions, Kroger failed to remediate. Former Kroger National Health and Wellness Director, Laura Raney had no knowledge of whether employee hours were increased or whether Kroger provided mandatory breaks as a result of the 2018 survey.[416] Additionally, Kroger did not eliminate or reduce pharmacy metrics.[417] Comments from the 2021 Kroger pharmacy survey echo the responses from the 2018 survey.[418] Kroger stores are still inadequately staffed; employees are still required to meet demanding pharmacy metrics and lack training resources; and patient safety remains an area of concern.

A number of national and international professional pharmacy and public health organizations have called for restrictions or an end to performance metrics that focus on high volume and speed because they cause distractions, impair professional judgment, and jeopardize patient safety and public health. In June 2013, NABP passed Resolution No: 109-7-13 "Performance Metrics and Quotas in the Practice of Pharmacy" to help "regulate, restrict, or prohibit the use in pharmacies of performance metrics or quotas that are proven to cause distractions and unsafe environments for pharmacists and technicians."[419] The resolution resulted from concerns expressed to a number of state boards of pharmacy by pharmacists about the impact on patient care caused by performance metrics that focused on time guarantees and percentage of prescriptions filled within a specified time period, for example. The member jurisdictions of NABP unanimously adopted the recommendation for NABP to assist its member boards of pharmacy to regulate, restrict, or prohibit the use in pharmacies of performance metrics or quotas that are proven to cause distractions and unsafe pharmacy environments.

In addition, a request was also made to the Institute for Safe Medication Practices (ISMP) to study the effect of performance metrics on patient care. ISMP is recognized for its medication safety information and worked with a number of boards of pharmacy to develop quality control standards and regulations. ISMP's advocacy work has resulted in numerous necessary changes in clinical practice, public policy, and drug labeling and packaging.

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[413] Kroger-MDL00153715.
[414] Kroger-MDL00153715 at 00153717-18; Kroger-MDL00153724; at 00153726.
[415] Kroger-MDL00153715 at 00153721-22.
[416] Raney II Dep., 177:11-178:13.
[417] *Id*. at 178:14-179:9.
[418] Kroger-MDL00129498; Raney II Dep., 350:23-351:20; KrogerWVAG00024849 (Raney Ex. 9) (88% of respondents disagreed that there is adequate staffing and 11% agreed that the workload allows them to get everything done in a safe and satisfactory manner).
[419] NABP, Performance Metrics and Quotas in the Practice of Pharmacy (Resolution 109-7-13) (June 5, 2013), https://nabp.pharmacy/performance-metrics-and-quotas-in-the-practice-of-pharmacy-resolution109-7-13/.

ISMP responded to NABP's request by collaborating with the American Pharmacist Association ("APhA"), the nation's oldest and largest professional organizations of pharmacists, and surveying community pharmacists, "The Community Pharmacy Time Guarantee Survey." Of the 673 community pharmacists who responded to the survey, 83% stated that they believed that distractions due to performance metrics or measure wait time contributed to dispensing errors and 49% felt specific time measurements were a significant contributing factor. Forty-five percent of the ISMP survey respondents worked in a chain pharmacy. Based on the survey results, ISMP stated that "the severity of the problem and the intensity of sentiments from pharmacists who work within such an environment call for a more in-depth exploration of the issue and discussion regarding how time guarantees impact patient safety and diminish the role of pharmacists in all practice settings."[420] In 2008, and again in 2011, ISMP warned that prescription guarantee times "jeopardize public health by discouraging pharmacists from spending time checking the patient's history and drug profile; checking for drug interactions, duplications, or other drug use evaluation concerns; calling physicians' offices for clarification; educating patients about the proper use of prescriptions; or any other critical function that promotes safety."[421]

NABP's 2013 Resolution also found that performance metrics, which measure the speed and efficiency of prescription workflow by such parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and the number of immunizations given per pharmacist shift, "may distract pharmacists and impair professional judgment." In addition, NABP found that the practice of applying performance metrics or quotas to pharmacists "may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions in the pharmacy."

In 2018, the House of Delegates of the APhA adopted the "Pharmacy Workplace Environment and Patient Safety" policy.[422] The policy states that APhA "opposes the setting and use of operational quotas or time-oriented metrics that negatively impact patient care and safety." Rather than impose performance metrics, APhA "supports staffing models that promote safe provision of patient care services and access to medications" and "encourages the adoption of patient-centered quality and performance measures that align with safe delivery of patient care services . . .."

The National Coordinating Council for Medication Error Reporting and Prevention ("NCCMERP"), also passed a statement advocating the "elimination of prescription time

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[420] Institute for Safe Medication Practices, Prescription Drug Time Guarantees and Their Impact on Patient Safety in Community Pharmacies. ISMP Medication Safety Alert! 2012 Sep; 18(17):1-4.

[421] Institute for Safe Medication Practices, Speed trap. ISMP Medication Safety Alert! Community/Ambulatory Care Edition 2008 Oct; 7(10):2-3 Institute for Safe Medication Practices, Return of the speed trap. ISMP Medication Safety Alert! Community/Ambulatory Care Edition 2011 Mar; 10(3):1.

[422] Actions of the 2018 American Pharmacists Association House of Delegates (March 2018), https://www.pharmacist.com/sites/default/files/files/2018%20Report%20of%20the%20APhA%20House%20of%20Delegates%20-%20FINAL.pdf.

guarantees and a strengthened focus on the clinical and safety activities of pharmacist within the community pharmacy setting."[423] "The Council believes prescription time guarantees and inducements . . . can be detrimental to patient safety. Forcing pharmacists to work quickly has the potential to lead to the development of at-risk behaviors that can rapidly become unsafe practice habits . . .. the added time pressures may discourage pharmacists from conducting critical clinical and safety checks which can result in medication errors."

The New Hampshire Board of Pharmacy sampled data from two retail chains in the state and found that pharmacists spend an average of 80 seconds on safety checks for each prescription filled. The president of the Board, Bob Stout, explained: "They're cutting corners where they think they can cut." "What happens, I found on the board, is people stop doing (safety) reviews." "They're not going in looking at patient records."

In response to the report, Thomas E. Menighan, the head of APhA, wrote "performance metrics that pressure pharmacists to work quickly" "contribute to a great deal of stress that can result in unintended patient harm."[424] A recent New York Times report discussed pharmacists who said, "the focus on metrics was a threat to patient safety" and "[m]etrics put unnecessary pressure on pharmacy staff to fill prescriptions as fast as possible, resulting in errors."[425] Some pharmacy errors can lead to death of a patient. Publix was among the pharmacies listed in the New York Times report. In 2018, a patient received a prescription for an antidepressant that was filled at Publix by a relative.[426] Instead of being dispensed the antidepressant that was prescribed, the patient received a strong chemotherapy drug.[427] Despite this egregious error, the relative reported that Publix claimed that it "already ha[d] systems in place" to prevent this type of error.[428] The patient died about two weeks after being dispensed the incorrect medication.[429]

A pharmacist pressured to work too quickly who misses dangerous drug interactions and does not have sufficient time to perform safety reviews is likewise at risk of missing red flags of diversion, including, for example, drug "cocktails" or other combinations of highly abused drugs described above. The high stress and chaotic environment created by arbitrary performance metrics is exacerbated by inadequate staffing at the Chain Pharmacies. Unreasonable volume and speed

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[423] National Coordinating Council for Medication Error Reporting and Prevention. Statement Advocating for the Elimination of Prescription Time Guarantees in Community Pharmacy, http://www.nccmerp.org/statement-advocating-elimination-prescription-time-guarantees-community-pharmacy.

[424] Pharmacists Provide Care, Fighting to let pharmacists keep patients safe, APhA, https://pharmacistsprovidecare.com/CEOBlog/fighting-let-pharmacists-keep-patients-safe.

[425] Ellen Gabler, How Chaos at Chain Pharmacies is Putting Patients at Risk, New York Times, Jan. 31, 2020, https://www.nytimes.com/2020/01/31/health/pharmacists-medication-errors.html (P-02302_00001).

[426] *Id*. at 8.

[427] *Id*. at 1.

[428] *Id*. at 8.

[429] *Id*. at 1.

demands on pharmacists coupled with too little staff means pharmacists cannot properly review prescriptions to ensure their appropriateness and validity and resolve all red flags.

In addition to state and national data related to pharmacy workloads, Kroger received articles as a member of the NACDS.[430] These articles include information related to mistakes made by pharmacists and dangerous work conditions.[431]

The New York Times report stated that "[i]n letters to state regulatory boards and in interviews with The New York Times, many pharmacists at companies like CVS, Rite Aid and Walgreens described understaffed and chaotic workplaces where they said it had become difficult to perform their jobs safely. . .."[432]

State boards of pharmacy also reported receiving complaints from pharmacists regarding workload, pharmacist and technician support, and performance metrics. The Oregon Board of Pharmacy surveyed pharmacists in 2012. The 1,300 responses identified workloads, distractions, and services designed to augment profits as major items of concern. Around the same time, the Iowa and North Carolina Boards of Pharmacy also examined the impact of the pharmacist workplace on patient care and medication errors. Most recently, the Ohio and California Boards of Pharmacy conducted and decided to conduct, respectively, surveys of pharmacists licensed by their boards. The Ohio Board of Pharmacy noted in its survey that, "[c]apturing this data is important as pharmacist working conditions have been identified as a concern among licensees, state regulators (several of which have issued similar surveys) and national organizations."[433]

The West Virginia's Board of Pharmacy conducted its own survey of pharmacists in West Virginia. Its results are similar to other pharmacists' responses across the country. In response to the inquiry of whether the pharmacist agrees that "my employer provides a work environment that allows for safe patient care," over 46% of respondents disagreed with that statement.[434] The comments expressed by survey respondents include chronic understaffing and "corporations are metric driven rather than patient safety or care driven." In response, to whether there was adequate time to complete their job in a safe and effective manner, over 62% of respondents disagreed. Kroger's internal survey results were worse than most pharmacists in the state of West Virginia that responded to the survey issued by the Board.

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[430] NACDS_FL_0024872; NACDS_FL_0024955.
[431] NACDS_FL_0024878 (Chicago Tribune article titled "Pharmacies miss half of dangerous drug combinations"); NACDS_FL_0024875 (article titled "Are more mistakes happening at pharmacies?"); NACDS_FL_0024888 (article titled "Risks Inherent in Pharmacists' Workloads Earn Attention of Legislators").
[432] *Id*.
[433] State of Ohio, Board of Pharmacy, Pharmacist Workload Survey, April 2021. https://www.aacp.org/article/2019-national-pharmacist-workforce-study.
[434] West Virginia Bd of Pharmacy Survey results, WVMLP-AG006116838.

In 2019, the Georgia Pharmacy Association, through Mercer University, initiated a pharmacist workload study.[435] This survey was created to examine "[p]harmacist workload and its correlation to patient outcomes and adverse medication events."[436] Some anonymous quotes from the survey indicate that performance goals directly influence pharmacy work environment and patient safety. One pharmacist stated that "[o]ur performance evaluations began to be tied to pharmacy metrics which set unattainable goals."[437] The pharmacist at this store were punished if they had multiple errors.[438] "This led to many of us not reporting errors."[439] Ultimately, "[t]his survey-formatted study concluded that there is a statistically significant risk of negative patient outcome when pharmacists are under high stress workloads."[440]

Despite the increase in performance metrics, the number of prescriptions dispensed per hour increased and staffing was reduced.[441] Defendants prioritized increasing business over patient safety. "Many Chain pharmacist are working 12 hours per day without additional pharmacist help and no designated food or bathroom breaks."[442] A comment received from the survey described that "the environment for the retail pharmacist consists of striving to meet unobtainable corporate metrics while also filling as many prescriptions as possible in the shortest amount of time and trying not to kill anyone."[443] Another pharmacist acknowledged that a fatigued pharmacist who is pulled in different directions will make mistakes. "We only pray that it is a 'small' mistake and not one that causes harm" or "takes a life." The demanding metrics of Chain Pharmacies negatively impact the pharmacy work environment and jeopardizes patient safety. One comment described how pharmacists are pushed to do "biometric and cholesterol screenings which pull us from the pharmacy. When you add in counseling patients on prescription and OTC medications, answering the hundreds of phone calls we get daily, calling the insurance company," "transferring prescriptions, calling the physicians," and running the register there leaves very little time to actually fill prescriptions and taking the time to research problems and personally talk to the patients."[444] The various pharmacy workload surveys indicate that pharmacy metrics are harmful

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[435] SDCGA_1202357 at 1202358 ("GPhA member Jonathan Hamrick needs your help with a research study on pharmacist workload.").
[436] Mercer University, https://www.surveymonkey.com/r/6NNXM22 (last visited Nov. 8, 2022).
[437] The Journal of the Georgia Pharmacy Association ("GPhA"), Georgia Pharmacy: The Future of Pharmacy - Pharmacy School Deans Weigh In, Feb./Mar. 2022, at 31 (hereafter "GPhA, The Future of Pharmacy").
[438] *Id*.
[439] *Id*.
[440] *Id*. (internal quotations omitted) (Pharmacists indicated that "they were concerned the increase in workload could result in a mistake that could harm their patients.").
[441] GPHA_Internal_00000004-1020 at 1051; GPHA, The Future of Pharmacy, at 31("In 2017, our labor metric was reconfigured, and staffing was drastically cut; pharmacist hours reduced from 190 to 160 per week, eliminating any pharmacist overlap.").
[442] GPHA_Internal_00000004-1020 at 1052.
[443] *Id*. at 1068.
[444] *Id*. at 1069-1070.

to patient safety. Pharmacists are pressured to meet performance goals at the expense of dispensing medication in a safe and effective manner.

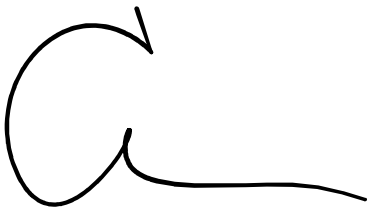
K. Conclusion

This opinion is based upon my review of information, data, documents referenced in this report, as well as my experience and expertise in the practice and regulation of pharmacy, and the usual and customary practice of pharmacy and pharmacy practices. It is my opinion that the Defendants and their pharmacists held, and continue to hold, a corresponding responsibility to only fill prescriptions for controlled substances that are issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice. Based on my review of the policies and procedures instituted by the Defendants governing pharmacy operations, Defendants' pharmacists' abilities to carry out their corresponding responsibility obligations were significantly impacted. Further, Defendants failed to provide their pharmacists with the data and tools necessary to fulfill their corresponding responsibility duties, including but not limited to, providing their pharmacists with access to dispensing data as well as the analysis of that data as it relates to red flags of diversion. The failure to provide such data resulted in significant quantities of controlled substances, particularly opioids, being dispersed outside of the closed distribution and dispensing system.

Corporate oversight includes established practices of pharmacies that should incorporate top-down compliance programs using data readily available to the corporation to guard against diversion. Corporate oversight should set patient care and integrity expectations and provide tools for pharmacists to exercise best practices to adhere to appropriate laws, regulations, and pharmacy standards of care in dispensing controlled substances. This report examined Defendants' actions with respect to maintaining effective policies and practices to guard against the diversion of prescription opioids, provision of important information and data to pharmacists in their pharmacies, well-established pharmacy standards of care, and the dispensing of opioids despite obvious and significant red flags.

Defendants were and remain aware of these requirements. Defendants delayed implementing controlled substance diversion policies and, when finally implemented, failed to monitor and enforce effective policies and procedures to guard against diversion. Instead, Defendants implemented and enforced employment evaluation policies and performance metrics that impeded their pharmacists' efforts to comply with laws and regulations and meet standards of care.

Respectfully submitted,



Carmen Catizone
Executed on January 24, 2024